

107TH CONGRESS
1ST SESSION

H. R. 526

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 8, 2001

Mr. GANSKE (for himself, Mr. DINGELL, Mr. LEACH, Mr. BERRY, Mrs. ROUKEMA, Mr. BROWN of Ohio, Mrs. MORELLA, Mr. JOHN, Mr. GILMAN, Mr. ANDREWS, Mr. LATOURETTE, Mr. RANGEL, Mr. STENHOLM, Mr. SANDLIN, Mr. STUPAK, Mr. PALLONE, Mr. TOWNS, Ms. ESHOO, Mrs. CAPPS, Mr. GREEN of Texas, Mr. GORDON, Ms. MCCARTHY of Missouri, Mr. ENGEL, Mr. MOORE, Mr. STICKLAND, Mr. MARKEY, Mr. SAWYER, Mrs. DAVIS of California, Mr. BARRETT, Mr. WYNN, Mr. STARK, Mr. WAXMAN, Mr. RUSH, Mr. BOUCHER, Mr. HALL of Texas, Mr. BISHOP, Mr. TURNER, Ms. HARMAN, Mr. PASCRELL, Mrs. MCCARTHY of New York, Mr. FRANK, Mr. MATSUI, Mr. COYNE, Mr. McDERMOTT, Mr. CARDIN, Mr. LEVIN, Mr. McNULTY, Mr. JEFFERSON, Mr. BECERRA, Mr. LEWIS of Georgia, Mr. KLECZKA, Mrs. THURMAN, Mr. BOSWELL, Mr. CROWLEY, Mr. TIERNEY, Mr. HOEFFEL, and Mr. MEEHAN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and the Workforce, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
 5 “Bipartisan Patient Protection Act of 2001”.

6 (b) TABLE OF CONTENTS.—The table of contents of
 7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—IMPROVING MANAGED CARE

Subtitle A—Utilization Review; Claims; and Internal and External Appeals

Sec. 101. Utilization review activities.

Sec. 102. Procedures for initial claims for benefits and prior authorization de-
 terminations.

Sec. 103. Internal appeals of claims denials.

Sec. 104. Independent external appeals procedures.

Subtitle B—Access to Care

Sec. 111. Consumer choice option.

Sec. 112. Choice of health care professional.

Sec. 113. Access to emergency care.

Sec. 114. Timely access to specialists.

Sec. 115. Patient access to obstetrical and gynecological care.

Sec. 116. Access to pediatric care.

Sec. 117. Continuity of care.

Sec. 118. Access to needed prescription drugs.

Sec. 119. Coverage for individuals participating in approved clinical trials.

Sec. 120. Required coverage for minimum hospital stay for mastectomies and
 lymph node dissections for the treatment of breast cancer and
 coverage for secondary consultations.

Subtitle C—Access to Information

Sec. 121. Patient access to information.

Subtitle D—Protecting the Doctor-Patient Relationship

Sec. 131. Prohibition of interference with certain medical communications.

Sec. 132. Prohibition of discrimination against providers based on licensure.

Sec. 133. Prohibition against improper incentive arrangements.

Sec. 134. Payment of claims.

Sec. 135. Protection for patient advocacy.

Subtitle E—Definitions

Sec. 151. Definitions.

- Sec. 152. Preemption; State flexibility; construction.
- Sec. 153. Exclusions.
- Sec. 154. Coverage of limited scope plans.
- Sec. 155. Regulations.
- Sec. 156. Incorporation into plan or coverage documents.

TITLE II—APPLICATION OF QUALITY CARE STANDARDS TO GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE UNDER THE PUBLIC HEALTH SERVICE ACT

- Sec. 201. Application to group health plans and group health insurance coverage.
- Sec. 202. Application to individual health insurance coverage.

TITLE III—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

- Sec. 301. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.
- Sec. 302. Availability of civil remedies.
- Sec. 303. Limitations on actions.

TITLE IV—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

Subtitle A—Application of Patient Protection Provisions

- Sec. 401. Application of requirements to group health plans under the Internal Revenue Code of 1986.
- Sec. 402. Conforming enforcement for women's health and cancer rights.

Subtitle B—Health Care Coverage Access Tax Incentives

- Sec. 411. Expanded availability of Archer MSAs.
- Sec. 412. Deduction for 100 percent of health insurance costs of self-employed individuals.
- Sec. 413. Credit for health insurance expenses of small businesses.
- Sec. 414. Certain grants by private foundations to qualified health benefit purchasing coalitions.
- Sec. 415. State grant program for market innovation.

TITLE V—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

- Sec. 501. Effective dates.
- Sec. 502. Coordination in implementation.
- Sec. 503. Severability.

1 **TITLE I—IMPROVING MANAGED**
2 **CARE**
3 **Subtitle A—Utilization Review;**
4 **Claims; and Internal and Exter-**
5 **nal Appeals**

6 **SEC. 101. UTILIZATION REVIEW ACTIVITIES.**

7 (a) COMPLIANCE WITH REQUIREMENTS.—

8 (1) IN GENERAL.—A group health plan, and a
9 health insurance issuer that provides health insur-
10 ance coverage, shall conduct utilization review activi-
11 ties in connection with the provision of benefits
12 under such plan or coverage only in accordance with
13 a utilization review program that meets the require-
14 ments of this section and section 102.

15 (2) USE OF OUTSIDE AGENTS.—Nothing in this
16 section shall be construed as preventing a group
17 health plan or health insurance issuer from arrang-
18 ing through a contract or otherwise for persons or
19 entities to conduct utilization review activities on be-
20 half of the plan or issuer, so long as such activities
21 are conducted in accordance with a utilization review
22 program that meets the requirements of this section.

23 (3) UTILIZATION REVIEW DEFINED.—For pur-
24 poses of this section, the terms “utilization review”
25 and “utilization review activities” mean procedures

1 used to monitor or evaluate the use or coverage,
2 clinical necessity, appropriateness, efficacy, or effi-
3 ciency of health care services, procedures or settings,
4 and includes prospective review, concurrent review,
5 second opinions, case management, discharge plan-
6 ning, or retrospective review.

7 (b) WRITTEN POLICIES AND CRITERIA.—

8 (1) WRITTEN POLICIES.—A utilization review
9 program shall be conducted consistent with written
10 policies and procedures that govern all aspects of the
11 program.

12 (2) USE OF WRITTEN CRITERIA.—

13 (A) IN GENERAL.—Such a program shall
14 utilize written clinical review criteria developed
15 with input from a range of appropriate actively
16 practicing health care professionals, as deter-
17 mined by the plan, pursuant to the program.
18 Such criteria shall include written clinical re-
19 view criteria that are based on valid clinical evi-
20 dence where available and that are directed spe-
21 cifically at meeting the needs of at-risk popu-
22 lations and covered individuals with chronic
23 conditions or severe illnesses, including gender-
24 specific criteria and pediatric-specific criteria
25 where available and appropriate.

1 (B) CONTINUING USE OF STANDARDS IN
2 RETROSPECTIVE REVIEW.—If a health care
3 service has been specifically pre-authorized or
4 approved for a participant, beneficiary, or en-
5 rollee under such a program, the program shall
6 not, pursuant to retrospective review, revise or
7 modify the specific standards, criteria, or proce-
8 dures used for the utilization review for proce-
9 dures, treatment, and services delivered to the
10 enrollee during the same course of treatment.

11 (C) REVIEW OF SAMPLE OF CLAIMS DENI-
12 ALS.—Such a program shall provide for a peri-
13 odic evaluation of the clinical appropriateness of
14 at least a sample of denials of claims for bene-
15 fits.

16 (c) CONDUCT OF PROGRAM ACTIVITIES.—

17 (1) ADMINISTRATION BY HEALTH CARE PRO-
18 FESSIONALS.—A utilization review program shall be
19 administered by qualified health care professionals
20 who shall oversee review decisions.

21 (2) USE OF QUALIFIED, INDEPENDENT PER-
22 SONNEL.—

23 (A) IN GENERAL.—A utilization review
24 program shall provide for the conduct of utiliza-
25 tion review activities only through personnel

1 who are qualified and have received appropriate
2 training in the conduct of such activities under
3 the program.

4 (B) PROHIBITION OF CONTINGENT COM-
5 PENSATION ARRANGEMENTS.—Such a program
6 shall not, with respect to utilization review ac-
7 tivities, permit or provide compensation or any-
8 thing of value to its employees, agents, or con-
9 tractors in a manner that encourages denials of
10 claims for benefits.

11 (C) PROHIBITION OF CONFLICTS.—Such a
12 program shall not permit a health care profes-
13 sional who is providing health care services to
14 an individual to perform utilization review ac-
15 tivities in connection with the health care serv-
16 ices being provided to the individual.

17 (3) ACCESSIBILITY OF REVIEW.—Such a pro-
18 gram shall provide that appropriate personnel per-
19 forming utilization review activities under the pro-
20 gram, including the utilization review administrator,
21 are reasonably accessible by toll-free telephone dur-
22 ing normal business hours to discuss patient care
23 and allow response to telephone requests, and that
24 appropriate provision is made to receive and respond
25 promptly to calls received during other hours.

1 (4) LIMITS ON FREQUENCY.—Such a program
2 shall not provide for the performance of utilization
3 review activities with respect to a class of services
4 furnished to an individual more frequently than is
5 reasonably required to assess whether the services
6 under review are medically necessary or appropriate.

7 **SEC. 102. PROCEDURES FOR INITIAL CLAIMS FOR BENE-**
8 **FITS AND PRIOR AUTHORIZATION DETER-**
9 **MINATIONS.**

10 (a) PROCEDURES OF INITIAL CLAIMS FOR BENE-
11 FITS.—

12 (1) IN GENERAL.—A group health plan, or
13 health insurance issuer offering health insurance
14 coverage, shall—

15 (A) make a determination on an initial
16 claim for benefits by a participant, beneficiary,
17 or enrollee (or authorized representative) re-
18 garding payment or coverage for items or serv-
19 ices under the terms and conditions of the plan
20 or coverage involved, including any cost-sharing
21 amount that the participant, beneficiary, or en-
22 rollee is required to pay with respect to such
23 claim for benefits; and

24 (B) notify a participant, beneficiary, or en-
25 rollee (or authorized representative) and the

1 treating health care professional involved re-
2 garding a determination on an initial claim for
3 benefits made under the terms and conditions
4 of the plan or coverage, including any cost-shar-
5 ing amounts that the participant, beneficiary,
6 or enrollee may be required to make with re-
7 spect to such claim for benefits, and of the
8 right of the participant, beneficiary, or enrollee
9 to an internal appeal under section 103.

10 (2) ACCESS TO INFORMATION.—

11 (A) TIMELY PROVISION OF NECESSARY IN-
12 FORMATION.—With respect to an initial claim
13 for benefits, the participant, beneficiary, or en-
14 rollee (or authorized representative) and the
15 treating health care professional (if any) shall
16 provide the plan or issuer with access to infor-
17 mation requested by the plan or issuer that is
18 necessary to make a determination relating to
19 the claim. Such access shall be provided not
20 later than 5 days after the date on which the
21 request for information is received, or, in a case
22 described in subparagraph (B) or (C) of sub-
23 section (b)(1), by such earlier time as may be
24 necessary to comply with the applicable timeline
25 under such subparagraph.

1 (B) LIMITED EFFECT OF FAILURE ON
2 PLAN OR ISSUER'S OBLIGATIONS.—Failure of
3 the participant, beneficiary, or enrollee to com-
4 ply with the requirements of subparagraph (A)
5 shall not remove the obligation of the plan or
6 issuer to make a decision in accordance with
7 the medical exigencies of the case and as soon
8 as possible, based on the available information,
9 and failure to comply with the time limit estab-
10 lished by this paragraph shall not remove the
11 obligation of the plan or issuer to comply with
12 the requirements of this section.

13 (3) ORAL REQUESTS.—In the case of a claim
14 for benefits involving an expedited or concurrent de-
15 termination, a participant, beneficiary, or enrollee
16 (or authorized representative) may make an initial
17 claim for benefits orally, but a group health plan, or
18 health insurance issuer offering health insurance
19 coverage, may require that the participant, bene-
20 ficiary, or enrollee (or authorized representative)
21 provide written confirmation of such request in a
22 timely manner on a form provided by the plan or
23 issuer. In the case of such an oral request for bene-
24 fits, the making of the request (and the timing of
25 such request) shall be treated as the making at that

1 time of a claims for such benefits without regard to
2 whether and when a written confirmation of such re-
3 quest is made.

4 (b) TIMELINE FOR MAKING DETERMINATIONS.—

5 (1) PRIOR AUTHORIZATION DETERMINATION.—

6 (A) IN GENERAL.—A group health plan, or
7 health insurance issuer offering health insur-
8 ance coverage, shall make a prior authorization
9 determination on a claim for benefits (whether
10 oral or written) in accordance with the medical
11 exigencies of the case and as soon as possible,
12 but in no case later than 14 days from the date
13 on which the plan or issuer receives information
14 that is reasonably necessary to enable the plan
15 or issuer to make a determination on the re-
16 quest for prior authorization and in no case
17 later than 28 days after the date of the claim
18 for benefits is received.

19 (B) EXPEDITED DETERMINATION.—Not-
20 withstanding subparagraph (A), a group health
21 plan, or health insurance issuer offering health
22 insurance coverage, shall expedite a prior au-
23 thorization determination on a claim for bene-
24 fits described in such subparagraph when a re-
25 quest for such an expedited determination is

1 made by a participant, beneficiary, or enrollee
2 (or authorized representative) at any time dur-
3 ing the process for making a determination and
4 a health care professional certifies, with the re-
5 quest, that a determination under the proce-
6 dures described in subparagraph (A) would seri-
7 ously jeopardize the life or health of the partici-
8 pant, beneficiary, or enrollee or the ability of
9 the participant, beneficiary, or enrollee to main-
10 tain or regain maximum function. Such deter-
11 mination shall be made in accordance with the
12 medical exigencies of the case and as soon as
13 possible, but in no case later than 72 hours
14 after the time the request is received by the
15 plan or issuer under this subparagraph.

16 (C) ONGOING CARE.—

17 (i) CONCURRENT REVIEW.—

18 (I) IN GENERAL.—Subject to
19 clause (ii), in the case of a concurrent
20 review of ongoing care (including hos-
21 pitalization), which results in a termi-
22 nation or reduction of such care, the
23 plan or issuer must provide by tele-
24 phone and in printed form notice of
25 the concurrent review determination

1 to the individual or the individual's
2 designee and the individual's health
3 care provider in accordance with the
4 medical exigencies of the case and as
5 soon as possible, with sufficient time
6 prior to the termination or reduction
7 to allow for an appeal under section
8 103(b)(3) to be completed before the
9 termination or reduction takes effect.

10 (II) CONTENTS OF NOTICE.—

11 Such notice shall include, with respect
12 to ongoing health care items and serv-
13 ices, the number of ongoing services
14 approved, the new total of approved
15 services, the date of onset of services,
16 and the next review date, if any, as
17 well as a statement of the individual's
18 rights to further appeal.

19 (ii) RULE OF CONSTRUCTION.—Clause

20 (i) shall not be construed as requiring
21 plans or issuers to provide coverage of care
22 that would exceed the coverage limitations
23 for such care.

24 (2) RETROSPECTIVE DETERMINATION.—A

25 group health plan, or health insurance issuer offer-

1 ing health insurance coverage, shall make a retro-
2 spective determination on a claim for benefits in ac-
3 cordance with the medical exigencies of the case and
4 as soon as possible, but not later than 30 days after
5 the date on which the plan or issuer receives infor-
6 mation that is reasonably necessary to enable the
7 plan or issuer to make a determination on the claim,
8 or, if earlier, 60 days after the date of receipt of the
9 claim for benefits.

10 (c) NOTICE OF A DENIAL OF A CLAIM FOR BENE-
11 FITS.—Written notice of a denial made under an initial
12 claim for benefits shall be issued to the participant, bene-
13 ficiary, or enrollee (or authorized representative) and the
14 treating health care professional in accordance with the
15 medical exigencies of the case and as soon as possible, but
16 in no case later than 2 days after the date of the deter-
17 mination (or, in the case described in subparagraph (B)
18 or (C) of subsection (b)(1), within the 72-hour or applica-
19 ble period referred to in such subparagraph).

20 (d) REQUIREMENTS OF NOTICE OF DETERMINA-
21 TIONS.—The written notice of a denial of a claim for bene-
22 fits determination under subsection (c) shall be provided
23 in printed form and written in a manner calculated to be
24 understood by the average participant, beneficiary, or en-
25 rollee and shall include—

1 (1) the specific reasons for the determination
2 (including a summary of the clinical or scientific evi-
3 dence used in making the determination);

4 (2) the procedures for obtaining additional in-
5 formation concerning the determination; and

6 (3) notification of the right to appeal the deter-
7 mination and instructions on how to initiate an ap-
8 peal in accordance with section 103.

9 (e) DEFINITIONS.—For purposes of this part:

10 (1) AUTHORIZED REPRESENTATIVE.—The term
11 “authorized representative” means, with respect to
12 an individual who is a participant, beneficiary, or en-
13 rollee, any health care professional or other person
14 acting on behalf of the individual with the individ-
15 ual’s consent or without such consent if the indi-
16 vidual is medically unable to provide such consent.

17 (2) CLAIM FOR BENEFITS.—The term “claim
18 for benefits” means any request for coverage (in-
19 cluding authorization of coverage), for eligibility, or
20 for payment in whole or in part, for an item or serv-
21 ice under a group health plan or health insurance
22 coverage.

23 (3) DENIAL OF CLAIM FOR BENEFITS.—The
24 term “denial” means, with respect to a claim for
25 benefits, a denial (in whole or in part) of, or a fail-

1 ure to act on a timely basis upon, the claim for ben-
2 efits and includes a failure to provide benefits (in-
3 cluding items and services) required to be provided
4 under this title.

5 (4) TREATING HEALTH CARE PROFESSIONAL.—

6 The term “treating health care professional” means,
7 with respect to services to be provided to a partici-
8 pant, beneficiary, or enrollee, a health care profes-
9 sional who is primarily responsible for delivering
10 those services to the participant, beneficiary, or en-
11 rollee.

12 **SEC. 103. INTERNAL APPEALS OF CLAIMS DENIALS.**

13 (a) RIGHT TO INTERNAL APPEAL.—

14 (1) IN GENERAL.—A participant, beneficiary, or
15 enrollee (or authorized representative) may appeal
16 any denial of a claim for benefits under section 102
17 under the procedures described in this section.

18 (2) TIME FOR APPEAL.—

19 (A) IN GENERAL.—A group health plan, or
20 health insurance issuer offering health insur-
21 ance coverage, shall ensure that a participant,
22 beneficiary, or enrollee (or authorized represent-
23 ative) has a period of not less than 180 days
24 beginning on the date of a denial of a claim for

1 benefits under section 102 in which to appeal
2 such denial under this section.

3 (B) DATE OF DENIAL.—For purposes of
4 subparagraph (A), the date of the denial shall
5 be deemed to be the date as of which the partic-
6 ipant, beneficiary, or enrollee knew of the denial
7 of the claim for benefits.

8 (3) FAILURE TO ACT.—The failure of a plan or
9 issuer to issue a determination on a claim for bene-
10 fits under section 102 within the applicable timeline
11 established for such a determination under such sec-
12 tion is a denial of a claim for benefits for purposes
13 this subtitle as of the date of the applicable deadline.

14 (4) PLAN WAIVER OF INTERNAL REVIEW.—A
15 group health plan, or health insurance issuer offer-
16 ing health insurance coverage, may waive the inter-
17 nal review process under this section. In such case
18 the plan or issuer shall provide notice to the partici-
19 pant, beneficiary, or enrollee (or authorized rep-
20 resentative) involved, the participant, beneficiary, or
21 enrollee (or authorized representative) involved shall
22 be relieved of any obligation to complete the internal
23 review involved, and may, at the option of such par-
24 ticipant, beneficiary, enrollee, or representative pro-

1 ceed directly to seek further appeal through external
2 review under section 104 or otherwise.

3 (b) TIMELINES FOR MAKING DETERMINATIONS.—

4 (1) ORAL REQUESTS.—In the case of an appeal
5 of a denial of a claim for benefits under this section
6 that involves an expedited or concurrent determina-
7 tion, a participant, beneficiary, or enrollee (or au-
8 thorized representative) may request such appeal
9 orally. A group health plan, or health insurance
10 issuer offering health insurance coverage, may re-
11 quire that the participant, beneficiary, or enrollee
12 (or authorized representative) provide written con-
13 firmation of such request in a timely manner on a
14 form provided by the plan or issuer. In the case of
15 such an oral request for an appeal of a denial, the
16 making of the request (and the timing of such re-
17 quest) shall be treated as the making at that time
18 of a request for an appeal without regard to whether
19 and when a written confirmation of such request is
20 made.

21 (2) ACCESS TO INFORMATION.—

22 (A) TIMELY PROVISION OF NECESSARY IN-
23 FORMATION.—With respect to an appeal of a
24 denial of a claim for benefits, the participant,
25 beneficiary, or enrollee (or authorized represent-

1 ative) and the treating health care professional
2 (if any) shall provide the plan or issuer with ac-
3 cess to information requested by the plan or
4 issuer that is necessary to make a determina-
5 tion relating to the appeal. Such access shall be
6 provided not later than 5 days after the date on
7 which the request for information is received,
8 or, in a case described in subparagraph (B) or
9 (C) of paragraph (3), by such earlier time as
10 may be necessary to comply with the applicable
11 timeline under such subparagraph.

12 (B) LIMITED EFFECT OF FAILURE ON
13 PLAN OR ISSUER'S OBLIGATIONS.—Failure of
14 the participant, beneficiary, or enrollee to com-
15 ply with the requirements of subparagraph (A)
16 shall not remove the obligation of the plan or
17 issuer to make a decision in accordance with
18 the medical exigencies of the case and as soon
19 as possible, based on the available information,
20 and failure to comply with the time limit estab-
21 lished by this paragraph shall not remove the
22 obligation of the plan or issuer to comply with
23 the requirements of this section.

24 (3) PRIOR AUTHORIZATION DETERMINA-
25 TIONS.—

1 (A) IN GENERAL.—A group health plan, or
2 health insurance issuer offering health insur-
3 ance coverage, shall make a determination on
4 an appeal of a denial of a claim for benefits
5 under this subsection in accordance with the
6 medical exigencies of the case and as soon as
7 possible, but in no case later than 14 days from
8 the date on which the plan or issuer receives
9 information that is reasonably necessary to en-
10 able the plan or issuer to make a determination
11 on the appeal and in no case later than 28 days
12 after the date the request for the appeal is re-
13 ceived.

14 (B) EXPEDITED DETERMINATION.—Not-
15 withstanding subparagraph (A), a group health
16 plan, or health insurance issuer offering health
17 insurance coverage, shall expedite a prior au-
18 thorization determination on an appeal of a de-
19 nial of a claim for benefits described in sub-
20 paragraph (A), when a request for such an ex-
21 pedited determination is made by a participant,
22 beneficiary, or enrollee (or authorized represent-
23 ative) at any time during the process for mak-
24 ing a determination and a health care profes-
25 sional certifies, with the request, that a deter-

1 mination under the procedures described in sub-
2 paragraph (A) would seriously jeopardize the
3 life or health of the participant, beneficiary, or
4 enrollee or the ability of the participant, bene-
5 ficiary, or enrollee to maintain or regain max-
6 imum function. Such determination shall be
7 made in accordance with the medical exigencies
8 of the case and as soon as possible, but in no
9 case later than 72 hours after the time the re-
10 quest for such appeal is received by the plan or
11 issuer under this subparagraph.

12 (C) ONGOING CARE DETERMINATIONS.—

13 (i) IN GENERAL.—Subject to clause
14 (ii), in the case of a concurrent review de-
15 termination described in section
16 102(b)(1)(C)(i)(I), which results in a ter-
17 mination or reduction of such care, the
18 plan or issuer must provide notice of the
19 determination on the appeal under this
20 section by telephone and in printed form to
21 the individual or the individual's designee
22 and the individual's health care provider in
23 accordance with the medical exigencies of
24 the case and as soon as possible, with suf-
25 ficient time prior to the termination or re-

duction to allow for an external appeal under section 104 to be completed before the termination or reduction takes effect.

(ii) RULE OF CONSTRUCTION.—Clause

(i) shall not be construed as requiring plans or issuers to provide coverage of care that would exceed the coverage limitations for such care.

(4) RETROSPECTIVE DETERMINATION.—A

group health plan, or health insurance issuer offering health insurance coverage, shall make a retrospective determination on an appeal of a claim for benefits in no case later than 30 days after the date on which the plan or issuer receives necessary information that is reasonably necessary to enable the plan or issuer to make a determination on the appeal and in no case later than 60 days after the date the request for the appeal is received.

(c) CONDUCT OF REVIEW.—

(1) IN GENERAL.—A review of a denial of a claim for benefits under this section shall be conducted by an individual with appropriate expertise who was not involved in the initial determination.

(2) REVIEW OF MEDICAL DECISIONS BY PHYSICIANS.—A review of an appeal of a denial of a claim

1 for benefits that is based on a lack of medical neces-
2 sity and appropriateness, or based on an experi-
3 mental or investigational treatment, or requires an
4 evaluation of medical facts, shall be made by a phy-
5 sician (allopathic or osteopathic) with appropriate
6 expertise (including, in the case of a child, appro-
7 priate pediatric expertise) who was not involved in
8 the initial determination.

9 (d) NOTICE OF DETERMINATION.—

10 (1) IN GENERAL.—Written notice of a deter-
11 mination made under an internal appeal of a denial
12 of a claim for benefits shall be issued to the partici-
13 pant, beneficiary, or enrollee (or authorized rep-
14 resentative) and the treating health care professional
15 in accordance with the medical exigencies of the case
16 and as soon as possible, but in no case later than
17 2 days after the date of completion of the review (or,
18 in the case described in subparagraph (B) or (C) of
19 subsection (b)(3), within the 72-hour or applicable
20 period referred to in such subparagraph).

21 (2) FINAL DETERMINATION.—The decision by a
22 plan or issuer under this section shall be treated as
23 the final determination of the plan or issuer on a de-
24 nial of a claim for benefits. The failure of a plan or
25 issuer to issue a determination on an appeal of a de-

1 nial of a claim for benefits under this section within
 2 the applicable timeline established for such a deter-
 3 mination shall be treated as a final determination on
 4 an appeal of a denial of a claim for benefits for pur-
 5 poses of proceeding to external review under section
 6 104.

7 (3) REQUIREMENTS OF NOTICE.—With respect
 8 to a determination made under this section, the no-
 9 tice described in paragraph (1) shall be provided in
 10 printed form and written in a manner calculated to
 11 be understood by the average participant, bene-
 12 ficiary, or enrollee and shall include—

13 (A) the specific reasons for the determina-
 14 tion (including a summary of the clinical or sci-
 15 entific evidence used in making the determina-
 16 tion);

17 (B) the procedures for obtaining additional
 18 information concerning the determination; and

19 (C) notification of the right to an inde-
 20 pendent external review under section 104 and
 21 instructions on how to initiate such a review.

22 **SEC. 104. INDEPENDENT EXTERNAL APPEALS PROCE-**
 23 **DURES.**

24 (a) RIGHT TO EXTERNAL APPEAL.—A group health
 25 plan, and a health insurance issuer offering health insur-

1 ance coverage, shall provide in accordance with this sec-
2 tion participants, beneficiaries, and enrollees (or author-
3 ized representatives) with access to an independent exter-
4 nal review for any denial of a claim for benefits.

5 (b) INITIATION OF THE INDEPENDENT EXTERNAL
6 REVIEW PROCESS.—

7 (1) TIME TO FILE.—A request for an inde-
8 pendent external review under this section shall be
9 filed with the plan or issuer not later than 180 days
10 after the date on which the participant, beneficiary,
11 or enrollee receives notice of the denial under section
12 103(d) or notice of waiver of internal review under
13 section 103(a)(4) or the date on which the plan or
14 issuer has failed to make a timely decision under
15 section 103(d)(2) and notifies the participant or
16 beneficiary that it has failed to make a timely deci-
17 sion and that the beneficiary must file an appeal
18 with an external review entity within 180 days if the
19 participant or beneficiary desires to file such an ap-
20 peal.

21 (2) FILING OF REQUEST.—

22 (A) IN GENERAL.—Subject to the suc-
23 ceeding provisions of this subsection, a group
24 health plan, and a health insurance issuer offer-
25 ing health insurance coverage, may—

1 (i) except as provided in subparagraph
2 (B)(i), require that a request for review be
3 in writing;

4 (ii) limit the filing of such a request
5 to the participant, beneficiary, or enrollee
6 involved (or an authorized representative);

7 (iii) except if waived by the plan or
8 issuer under section 103(a)(4), condition
9 access to an independent external review
10 under this section upon a final determina-
11 tion of a denial of a claim for benefits
12 under the internal review procedure under
13 section 103;

14 (iv) except as provided in subpara-
15 graph (B)(ii), require payment of a filing
16 fee to the plan or issuer of a sum that does
17 not exceed \$25; and

18 (v) require that a request for review
19 include the consent of the participant, ben-
20 eficiary, or enrollee (or authorized rep-
21 resentative) for the release of necessary
22 medical information or records of the par-
23 ticipant, beneficiary, or enrollee to the
24 qualified external review entity only for

1 purposes of conducting external review ac-
2 tivities.

3 (B) REQUIREMENTS AND EXCEPTION RE-
4 LATING TO GENERAL RULE.—

5 (i) ORAL REQUESTS PERMITTED IN
6 EXPEDITED OR CONCURRENT CASES.—In
7 the case of an expedited or concurrent ex-
8 ternal review as provided for under sub-
9 section (e), the request may be made oral-
10 ly. A group health plan, or health insur-
11 ance issuer offering health insurance cov-
12 erage, may require that the participant,
13 beneficiary, or enrollee (or authorized rep-
14 resentative) provide written confirmation
15 of such request in a timely manner on a
16 form provided by the plan or issuer. Such
17 written confirmation shall be treated as a
18 consent for purposes of subparagraph
19 (A)(v). In the case of such an oral request
20 for such a review, the making of the re-
21 quest (and the timing of such request)
22 shall be treated as the making at that time
23 of a request for such an external review
24 without regard to whether and when a

1 written confirmation of such request is
2 made.

3 (ii) EXCEPTION TO FILING FEE RE-
4 QUIREMENT.—

5 (I) INDIGENCY.—Payment of a
6 filing fee shall not be required under
7 subparagraph (A)(iv) where there is a
8 certification (in a form and manner
9 specified in guidelines established by
10 the appropriate Secretary) that the
11 participant, beneficiary, or enrollee is
12 indigent (as defined in such guide-
13 lines).

14 (II) FEE NOT REQUIRED.—Pay-
15 ment of a filing fee shall not be re-
16 quired under subparagraph (A)(iv) if
17 the plan or issuer waives the internal
18 appeals process under section
19 103(a)(4).

20 (III) REFUNDING OF FEE.—The
21 filing fee paid under subparagraph
22 (A)(iv) shall be refunded if the deter-
23 mination under the independent exter-
24 nal review is to reverse or modify the

1 denial which is the subject of the re-
2 view.

3 (IV) COLLECTION OF FILING
4 FEE.—The failure to pay such a filing
5 fee shall not prevent the consideration
6 of a request for review but, subject to
7 the preceding provisions of this clause,
8 shall constitute a legal liability to pay.

9 (c) REFERRAL TO QUALIFIED EXTERNAL REVIEW
10 ENTITY UPON REQUEST.—

11 (1) IN GENERAL.—Upon the filing of a request
12 for independent external review with the group
13 health plan, or health insurance issuer offering
14 health insurance coverage, the plan or issuer shall
15 immediately refer such request, and forward the
16 plan or issuer's initial decision (including the infor-
17 mation described in section 103(d)(3)(A)), to a
18 qualified external review entity selected in accord-
19 ance with this section.

20 (2) ACCESS TO PLAN OR ISSUER AND HEALTH
21 PROFESSIONAL INFORMATION.—With respect to an
22 independent external review conducted under this
23 section, the participant, beneficiary, or enrollee (or
24 authorized representative), the plan or issuer, and
25 the treating health care professional (if any) shall

1 provide the external review entity with information
2 that is necessary to conduct a review under this sec-
3 tion, as determined and requested by the entity.
4 Such information shall be provided not later than 5
5 days after the date on which the request for infor-
6 mation is received, or, in a case described in clause
7 (ii) or (iii) of subsection (e)(1)(A), by such earlier
8 time as may be necessary to comply with the appli-
9 cable timeline under such clause.

10 (3) SCREENING OF REQUESTS BY QUALIFIED
11 EXTERNAL REVIEW ENTITIES.—

12 (A) IN GENERAL.—With respect to a re-
13 quest referred to a qualified external review en-
14 tity under paragraph (1) relating to a denial of
15 a claim for benefits, the entity shall refer such
16 request for the conduct of an independent med-
17 ical review unless the entity determines that—

18 (i) any of the conditions described in
19 clauses (ii) or (iii) of subsection (b)(2)(A)
20 have not been met;

21 (ii) the denial of the claim for benefits
22 does not involve a medically reviewable de-
23 cision under subsection (d)(2);

24 (iii) the denial of the claim for bene-
25 fits relates to a decision regarding whether

1 an individual is a participant, beneficiary,
2 or enrollee who is enrolled under the terms
3 and conditions of the plan or coverage (in-
4 cluding the applicability of any waiting pe-
5 riod under the plan or coverage); or

6 (iv) the denial of the claim for bene-
7 fits is a decision as to the application of
8 cost-sharing requirements or the applica-
9 tion of a specific exclusion or express limi-
10 tation on the amount, duration, or scope of
11 coverage of items or services under the
12 terms and conditions of the plan or cov-
13 erage unless the decision is a denial de-
14 scribed in subsection (d)(2).

15 Upon making a determination that any of
16 clauses (i) through (iv) applies with respect to
17 the request, the entity shall determine that the
18 denial of a claim for benefits involved is not eli-
19 gible for independent medical review under sub-
20 section (d), and shall provide notice in accord-
21 ance with subparagraph (C).

22 (B) PROCESS FOR MAKING DETERMINA-
23 TIONS.—

24 (i) NO DEFERENCE TO PRIOR DETER-
25 MINATIONS.—In making determinations

1 under subparagraph (A), there shall be no
2 deference given to determinations made by
3 the plan or issuer or the recommendation
4 of a treating health care professional (if
5 any).

6 (ii) USE OF APPROPRIATE PER-
7 SONNEL.—A qualified external review enti-
8 ty shall use appropriately qualified per-
9 sonnel to make determinations under this
10 section.

11 (C) NOTICES AND GENERAL TIMELINES
12 FOR DETERMINATION.—

13 (i) NOTICE IN CASE OF DENIAL OF
14 REFERRAL.—If the entity under this para-
15 graph does not make a referral to an inde-
16 pendent medical reviewer, the entity shall
17 provide notice to the plan or issuer, the
18 participant, beneficiary, or enrollee (or au-
19 thorized representative) filing the request,
20 and the treating health care professional
21 (if any) that the denial is not subject to
22 independent medical review. Such notice—

23 (I) shall be written (and, in addi-
24 tion, may be provided orally) in a

1 manner calculated to be understood
2 by an average participant or enrollee;

3 (II) shall include the reasons for
4 the determination;

5 (III) include any relevant terms
6 and conditions of the plan or cov-
7 erage; and

8 (IV) include a description of any
9 further recourse available to the indi-
10 vidual.

11 (ii) GENERAL TIMELINE FOR DETER-
12 MINATIONS.—Upon receipt of information
13 under paragraph (2), the qualified external
14 review entity, and if required the inde-
15 pendent medical reviewer, shall make a de-
16 termination within the overall timeline that
17 is applicable to the case under review as
18 described in subsection (e), except that if
19 the entity determines that a referral to an
20 independent medical reviewer is not re-
21 quired, the entity shall provide notice of
22 such determination to the participant, ben-
23 eficiary, or enrollee (or authorized rep-
24 resentative) within such timeline and with-

1 in 2 days of the date of such determina-
2 tion.

3 (d) INDEPENDENT MEDICAL REVIEW.—

4 (1) IN GENERAL.—If a qualified external review
5 entity determines under subsection (c) that a denial
6 of a claim for benefits is eligible for independent
7 medical review, the entity shall refer the denial in-
8 volved to an independent medical reviewer for the
9 conduct of an independent medical review under this
10 subsection.

11 (2) MEDICALLY REVIEWABLE DECISIONS.—A
12 denial of a claim for benefits is eligible for inde-
13 pendent medical review if the benefit for the item or
14 service for which the claim is made would be a cov-
15 ered benefit under the terms and conditions of the
16 plan or coverage but for one (or more) of the fol-
17 lowing determinations:

18 (A) DENIALS BASED ON MEDICAL NECES-
19 SITY AND APPROPRIATENESS.—A determination
20 that the item or service is not covered because
21 it is not medically necessary and appropriate or
22 based on the application of substantially equiva-
23 lent terms.

24 (B) DENIALS BASED ON EXPERIMENTAL
25 OR INVESTIGATIONAL TREATMENT.—A deter-

1 mination that the item or service is not covered
2 because it is experimental or investigational or
3 based on the application of substantially equivalent
4 terms.

5 (C) DENIALS OTHERWISE BASED ON AN
6 EVALUATION OF MEDICAL FACTS.—A determination
7 mination that the item or service or condition
8 is not covered based on grounds that require an
9 evaluation of the medical facts by a health care
10 professional in the specific case involved to determine
11 the coverage and extent of coverage of
12 the item or service or condition.

13 (3) INDEPENDENT MEDICAL REVIEW DETER-
14 MINATION.—

15 (A) IN GENERAL.—An independent medical
16 reviewer under this section shall make a
17 new independent determination with respect to
18 whether or not the denial of a claim for a benefit
19 that is the subject of the review should be
20 upheld, reversed, or modified.

21 (B) STANDARD FOR DETERMINATION.—
22 The independent medical reviewer's determination
23 relating to the medical necessity and appropriateness,
24 or the experimental or investigation nature, or the evaluation of the medical
25

1 facts of the item, service, or condition shall be
2 based on the medical condition of the partici-
3 pant, beneficiary, or enrollee (including the
4 medical records of the participant, beneficiary,
5 or enrollee) and valid, relevant scientific evi-
6 dence and clinical evidence, including peer-re-
7 viewed medical literature or findings and in-
8 cluding expert opinion.

9 (C) NO COVERAGE FOR EXCLUDED BENE-
10 FITS.—Nothing in this subsection shall be con-
11 strued to permit an independent medical re-
12 viewer to require that a group health plan, or
13 health insurance issuer offering health insur-
14 ance coverage, provide coverage for items or
15 services for which benefits are specifically ex-
16 cluded or expressly limited under the plan or
17 coverage in the plain language of the plan docu-
18 ment (and which are disclosed under section
19 121(b)(1)(C)) except to the extent that the ap-
20 plication or interpretation of the exclusion or
21 limitation involves a determination described in
22 paragraph (2).

23 (D) EVIDENCE AND INFORMATION TO BE
24 USED IN MEDICAL REVIEWS.—In making a de-
25 termination under this subsection, the inde-

pendent medical reviewer shall also consider appropriate and available evidence and information, including the following:

(i) The determination made by the plan or issuer with respect to the claim upon internal review and the evidence, guidelines, or rationale used by the plan or issuer in reaching such determination.

(ii) The recommendation of the treating health care professional and the evidence, guidelines, and rationale used by the treating health care professional in reaching such recommendation.

(iii) Additional relevant evidence or information obtained by the reviewer or submitted by the plan, issuer, participant, beneficiary, or enrollee (or an authorized representative), or treating health care professional.

(iv) The plan or coverage document.

(E) INDEPENDENT DETERMINATION.—In making determinations under this subtitle, a qualified external review entity and an independent medical reviewer shall—

1 (i) consider the claim under review
2 without deference to the determinations
3 made by the plan or issuer or the rec-
4 ommendation of the treating health care
5 professional (if any); and

6 (ii) consider, but not be bound by the
7 definition used by the plan or issuer of
8 “medically necessary and appropriate”, or
9 “experimental or investigational”, or other
10 substantially equivalent terms that are
11 used by the plan or issuer to describe med-
12 ical necessity and appropriateness or ex-
13 perimental or investigational nature of the
14 treatment.

15 (F) DETERMINATION OF INDEPENDENT
16 MEDICAL REVIEWER.—An independent medical
17 reviewer shall, in accordance with the deadlines
18 described in subsection (e), prepare a written
19 determination to uphold, reverse, or modify the
20 denial under review. Such written determination
21 shall include—

22 (i) the determination of the reviewer;
23 (ii) the specific reasons of the re-
24 viewer for such determination, including a
25 summary of the clinical or scientific evi-

dence used in making the determination;
and

(iii) with respect to a determination to
reverse or modify the denial under review,
a timeframe within which the plan or
issuer must comply with such determina-
tion.

(G) NONBINDING NATURE OF ADDITIONAL
RECOMMENDATIONS.—In addition to the deter-
mination under subparagraph (F), the reviewer
may provide the plan or issuer and the treating
health care professional with additional rec-
ommendations in connection with such a deter-
mination, but any such recommendations shall
not affect (or be treated as part of) the deter-
mination and shall not be binding on the plan
or issuer.

(e) TIMELINES AND NOTIFICATIONS.—

(1) TIMELINES FOR INDEPENDENT MEDICAL
REVIEW.—

(A) PRIOR AUTHORIZATION DETERMINA-
TION.—

(i) IN GENERAL.—The independent
medical reviewer (or reviewers) shall make
a determination on a denial of a claim for

1 benefits that is referred to the reviewer
2 under subsection (c)(3) in accordance with
3 the medical exigencies of the case and as
4 soon as possible, but in no case later than
5 14 days after the date of receipt of infor-
6 mation under subsection (c)(2) if the re-
7 view involves a prior authorization of items
8 or services and in no case later than 21
9 days after the date the request for external
10 review is received.

11 (ii) EXPEDITED DETERMINATION.—

12 Notwithstanding clause (i) and subject to
13 clause (iii), the independent medical re-
14 viewer (or reviewers) shall make an expe-
15 dited determination on a denial of a claim
16 for benefits described in clause (i), when a
17 request for such an expedited determina-
18 tion is made by a participant, beneficiary,
19 or enrollee (or authorized representative)
20 at any time during the process for making
21 a determination, and a health care profes-
22 sional certifies, with the request, that a de-
23 termination under the timeline described in
24 clause (i) would seriously jeopardize the
25 life or health of the participant, bene-

1 fiary, or enrollee or the ability of the par-
2 ticipant, beneficiary, or enrollee to main-
3 tain or regain maximum function. Such de-
4 termination shall be made as soon in ac-
5 cordance with the medical exigencies of the
6 case and as soon as possible, but in no
7 case later than 72 hours after the time the
8 request for external review is received by
9 the qualified external review entity.

10 (iii) ONGOING CARE DETERMINA-
11 TION.—Notwithstanding clause (i), in the
12 case of a review described in such sub-
13 clause that involves a termination or reduc-
14 tion of care, the notice of the determina-
15 tion shall be completed not later than 24
16 hours after the time the request for exter-
17 nal review is received by the qualified ex-
18 ternal review entity and before the end of
19 the approved period of care.

20 (B) RETROSPECTIVE DETERMINATION.—

21 The independent medical reviewer (or review-
22 ers) shall complete a review in the case of a ret-
23 rospective determination on an appeal of a de-
24 nial of a claim for benefits that is referred to
25 the reviewer under subsection (c)(3) in no case

1 later than 30 days after the date of receipt of
2 information under subsection (c)(2) and in no
3 case later than 60 days after the date the re-
4 quest for external review is received by the
5 qualified external review entity.

6 (2) NOTIFICATION OF DETERMINATION.—The
7 external review entity shall ensure that the plan or
8 issuer, the participant, beneficiary, or enrollee (or
9 authorized representative) and the treating health
10 care professional (if any) receives a copy of the writ-
11 ten determination of the independent medical re-
12 viewer prepared under subsection (d)(3)(F). Nothing
13 in this paragraph shall be construed as preventing
14 an entity or reviewer from providing an initial oral
15 notice of the reviewer’s determination.

16 (3) FORM OF NOTICES.—Determinations and
17 notices under this subsection shall be written in a
18 manner calculated to be understood by an average
19 participant.

20 (f) COMPLIANCE.—

21 (1) APPLICATION OF DETERMINATIONS.—

22 (A) EXTERNAL REVIEW DETERMINATIONS
23 BINDING ON PLAN.—The determinations of an
24 external review entity and an independent med-

1 ical reviewer under this section shall be binding
2 upon the plan or issuer involved.

3 (B) COMPLIANCE WITH DETERMINA-
4 TION.—If the determination of an independent
5 medical reviewer is to reverse or modify the de-
6 nial, the plan or issuer, upon the receipt of such
7 determination, shall authorize coverage to com-
8 ply with the medical reviewer’s determination in
9 accordance with the timeframe established by
10 the medical reviewer.

11 (2) FAILURE TO COMPLY.—

12 (A) IN GENERAL.—If a plan or issuer fails
13 to comply with the timeframe established under
14 paragraph (1)(B) with respect to a participant,
15 beneficiary, or enrollee, where such failure to
16 comply is caused by the plan or issuer, the par-
17 ticipant, beneficiary, or enrollee may obtain the
18 items or services involved (in a manner con-
19 sistent with the determination of the inde-
20 pendent external reviewer) from any provider
21 regardless of whether such provider is a partici-
22 pating provider under the plan or coverage.

23 (B) REIMBURSEMENT.—

24 (i) IN GENERAL.—Where a partici-
25 pant, beneficiary, or enrollee obtains items

1 or services in accordance with subpara-
2 graph (A), the plan or issuer involved shall
3 provide for reimbursement of the costs of
4 such items or services. Such reimburse-
5 ment shall be made to the treating health
6 care professional or to the participant, ben-
7 eficiary, or enrollee (in the case of a partic-
8 ipant, beneficiary, or enrollee who pays for
9 the costs of such items or services).

10 (ii) AMOUNT.—The plan or issuer
11 shall fully reimburse a professional, partici-
12 pant, beneficiary, or enrollee under clause
13 (i) for the total costs of the items or serv-
14 ices provided (regardless of any plan limi-
15 tations that may apply to the coverage of
16 such items or services) so long as the items
17 or services were provided in a manner con-
18 sistent with the determination of the inde-
19 pendent medical reviewer.

20 (C) FAILURE TO REIMBURSE.—Where a
21 plan or issuer fails to provide reimbursement to
22 a professional, participant, beneficiary, or en-
23 rollee in accordance with this paragraph, the
24 professional, participant, beneficiary, or enrollee
25 may commence a civil action (or utilize other

1 remedies available under law) to recover only
2 the amount of any such reimbursement that is
3 owed by the plan or issuer and any necessary
4 legal costs or expenses (including attorney's
5 fees) incurred in recovering such reimburse-
6 ment.

7 (D) AVAILABLE REMEDIES.—The remedies
8 provided under this paragraph are in addition
9 to any other available remedies.

10 (3) PENALTIES AGAINST AUTHORIZED OFFI-
11 CIALS FOR REFUSING TO AUTHORIZE THE DETER-
12 MINATION OF AN EXTERNAL REVIEW ENTITY.—

13 (A) MONETARY PENALTIES.—

14 (i) IN GENERAL.—In any case in
15 which the determination of an external re-
16 view entity is not followed by a group
17 health plan, or by a health insurance issuer
18 offering health insurance coverage, any
19 person who, acting in the capacity of au-
20 thorizing the benefit, causes such refusal
21 may, in the discretion in a court of com-
22 petent jurisdiction, be liable to an ag-
23 grieved participant, beneficiary, or enrollee
24 for a civil penalty in an amount of up to
25 \$1,000 a day from the date on which the

determination was transmitted to the plan or issuer by the external review entity until the date the refusal to provide the benefit is corrected.

(ii) ADDITIONAL PENALTY FOR FAILING TO FOLLOW TIMELINE.—In any case in which treatment was not commenced by the plan in accordance with the determination of an independent external reviewer, the Secretary shall assess a civil penalty of \$10,000 against the plan and the plan shall pay such penalty to the participant, beneficiary, or enrollee involved.

(B) CEASE AND DESIST ORDER AND ORDER OF ATTORNEY'S FEES.—In any action described in subparagraph (A) brought by a participant, beneficiary, or enrollee with respect to a group health plan, or a health insurance issuer offering health insurance coverage, in which a plaintiff alleges that a person referred to in such subparagraph has taken an action resulting in a refusal of a benefit determined by an external appeal entity to be covered, or has failed to take an action for which such person is responsible under the terms and conditions of

1 the plan or coverage and which is necessary
2 under the plan or coverage for authorizing a
3 benefit, the court shall cause to be served on
4 the defendant an order requiring the
5 defendant—

6 (i) to cease and desist from the al-
7 leged action or failure to act; and

8 (ii) to pay to the plaintiff a reasonable
9 attorney's fee and other reasonable costs
10 relating to the prosecution of the action on
11 the charges on which the plaintiff prevails.

12 (C) ADDITIONAL CIVIL PENALTIES.—

13 (i) IN GENERAL.—In addition to any
14 penalty imposed under subparagraph (A)
15 or (B), the appropriate Secretary may as-
16 sess a civil penalty against a person acting
17 in the capacity of authorizing a benefit de-
18 termined by an external review entity for
19 one or more group health plans, or health
20 insurance issuers offering health insurance
21 coverage, for—

22 (I) any pattern or practice of re-
23 peated refusal to authorize a benefit
24 determined by an external appeal enti-
25 ty to be covered; or

1 (II) any pattern or practice of re-
2 peated violations of the requirements
3 of this section with respect to such
4 plan or coverage.

5 (ii) STANDARD OF PROOF AND
6 AMOUNT OF PENALTY.—Such penalty shall
7 be payable only upon proof by clear and
8 convincing evidence of such pattern or
9 practice and shall be in an amount not to
10 exceed the lesser of—

11 (I) 25 percent of the aggregate
12 value of benefits shown by the appro-
13 priate Secretary to have not been pro-
14 vided, or unlawfully delayed, in viola-
15 tion of this section under such pattern
16 or practice; or

17 (II) \$500,000.

18 (D) REMOVAL AND DISQUALIFICATION.—
19 Any person acting in the capacity of author-
20 izing benefits who has engaged in any such pat-
21 tern or practice described in subparagraph
22 (C)(i) with respect to a plan or coverage, upon
23 the petition of the appropriate Secretary, may
24 be removed by the court from such position,
25 and from any other involvement, with respect to

1 such a plan or coverage, and may be precluded
2 from returning to any such position or involve-
3 ment for a period determined by the court.

4 (4) PROTECTION OF LEGAL RIGHTS.—Nothing
5 in this subsection or subtitle shall be construed as
6 altering or eliminating any cause of action or legal
7 rights or remedies of participants, beneficiaries, en-
8 rollees, and others under State or Federal law (in-
9 cluding sections 502 and 503 of the Employee Re-
10 tirement Income Security Act of 1974), including
11 the right to file judicial actions to enforce rights.

12 (g) QUALIFICATIONS OF INDEPENDENT MEDICAL
13 REVIEWERS.—

14 (1) IN GENERAL.—In referring a denial to 1 or
15 more individuals to conduct independent medical re-
16 view under subsection (c), the qualified external re-
17 view entity shall ensure that—

18 (A) each independent medical reviewer
19 meets the qualifications described in paragraphs
20 (2) and (3);

21 (B) with respect to each review at least 1
22 such reviewer meets the requirements described
23 in paragraphs (4) and (5); and

24 (C) compensation provided by the entity to
25 the reviewer is consistent with paragraph (6).

1 (2) LICENSURE AND EXPERTISE.—Each inde-
2 pendent medical reviewer shall be a physician
3 (allopathic or osteopathic) or health care profes-
4 sional who—

5 (A) is appropriately credentialed or li-
6 censed in 1 or more States to deliver health
7 care services; and

8 (B) typically treats the condition, makes
9 the diagnosis, or provides the type of treatment
10 under review.

11 (3) INDEPENDENCE.—

12 (A) IN GENERAL.—Subject to subpara-
13 graph (B), each independent medical reviewer
14 in a case shall—

15 (i) not be a related party (as defined
16 in paragraph (7));

17 (ii) not have a material familial, fi-
18 nancial, or professional relationship with
19 such a party; and

20 (iii) not otherwise have a conflict of
21 interest with such a party (as determined
22 under regulations).

23 (B) EXCEPTION.—Nothing in subpara-
24 graph (A) shall be construed to—

1 (i) prohibit an individual, solely on the
2 basis of affiliation with the plan or issuer,
3 from serving as an independent medical re-
4 viewer if—

5 (I) a non-affiliated individual is
6 not reasonably available;

7 (II) the affiliated individual is
8 not involved in the provision of items
9 or services in the case under review;

10 (III) the fact of such an affili-
11 ation is disclosed to the plan or issuer
12 and the participant, beneficiary, or
13 enrollee (or authorized representative)
14 and neither party objects; and

15 (IV) the affiliated individual is
16 not an employee of the plan or issuer
17 and does not provide services exclu-
18 sively or primarily to or on behalf of
19 the plan or issuer;

20 (ii) prohibit an individual who has
21 staff privileges at the institution where the
22 treatment involved takes place from serv-
23 ing as an independent medical reviewer
24 merely on the basis of such affiliation if
25 the affiliation is disclosed to the plan or

1 issuer and the participant, beneficiary, or
2 enrollee (or authorized representative), and
3 neither party objects; or

4 (iii) prohibit receipt of compensation
5 by an independent medical reviewer from
6 an entity if the compensation is provided
7 consistent with paragraph (6).

8 (4) PRACTICING HEALTH CARE PROFESSIONAL
9 IN SAME FIELD.—

10 (A) IN GENERAL.—In a case involving
11 treatment, or the provision of items or
12 services—

13 (i) by a physician, a reviewer shall be
14 a practicing physician (allopathic or osteo-
15 pathic) of the same or similar specialty, as
16 a physician who typically treats the condi-
17 tion, makes the diagnosis, or provides the
18 type of treatment under review; or

19 (ii) by a health care professional
20 (other than a physician), a reviewer shall
21 be a practicing physician (allopathic or os-
22 teopathic) or, if determined appropriate by
23 the qualified external review entity, a prac-
24 ticing health care professional (other than
25 such a physician), of the same or similar

1 specialty as the health care professional
2 who typically treats the condition, makes
3 the diagnosis, or provides the type of treat-
4 ment under review.

5 (B) PRACTICING DEFINED.—For purposes
6 of this paragraph, the term “practicing” means,
7 with respect to an individual who is a physician
8 or other health care professional that the indi-
9 vidual provides health care services to individual
10 patients on average at least 2 days per week.

11 (5) PEDIATRIC EXPERTISE.—In the case of an
12 external review relating to a child, a reviewer shall
13 have expertise under paragraph (2) in pediatrics.

14 (6) LIMITATIONS ON REVIEWER COMPENSA-
15 TION.—Compensation provided by a qualified exter-
16 nal review entity to an independent medical reviewer
17 in connection with a review under this section
18 shall—

19 (A) not exceed a reasonable level; and

20 (B) not be contingent on the decision ren-
21 dered by the reviewer.

22 (7) RELATED PARTY DEFINED.—For purposes
23 of this section, the term “related party” means, with
24 respect to a denial of a claim under a plan or cov-

erage relating to a participant, beneficiary, or enrollee, any of the following:

(A) The plan, plan sponsor, or issuer involved, or any fiduciary, officer, director, or employee of such plan, plan sponsor, or issuer.

(B) The participant, beneficiary, or enrollee (or authorized representative).

(C) The health care professional that provides the items or services involved in the denial.

(D) The institution at which the items or services (or treatment) involved in the denial are provided.

(E) The manufacturer of any drug or other item that is included in the items or services involved in the denial.

(F) Any other party determined under any regulations to have a substantial interest in the denial involved.

(h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

(1) SELECTION OF QUALIFIED EXTERNAL REVIEW ENTITIES.—

(A) LIMITATION ON PLAN OR ISSUER SELECTION.—The appropriate Secretary shall implement procedures—

1 (i) to assure that the selection process
2 among qualified external review entities
3 will not create any incentives for external
4 review entities to make a decision in a bi-
5 ased manner; and

6 (ii) for auditing a sample of decisions
7 by such entities to assure that no such de-
8 cisions are made in a biased manner.

9 No such selection process under the procedures
10 implemented by the appropriate Secretary may
11 give either the patient or the plan or issuer any
12 ability to determine or influence the selection of
13 a qualified external review entity to review the
14 case of any participant, beneficiary, or enrollee.

15 (B) STATE AUTHORITY WITH RESPECT TO
16 QUALIFIED EXTERNAL REVIEW ENTITIES FOR
17 HEALTH INSURANCE ISSUERS.—With respect to
18 health insurance issuers offering health insur-
19 ance coverage in a State, the State may provide
20 for external review activities to be conducted by
21 a qualified external appeal entity that is des-
22 ignated by the State or that is selected by the
23 State in a manner determined by the State to
24 assure an unbiased determination.

1 (2) CONTRACT WITH QUALIFIED EXTERNAL RE-
2 VIEW ENTITY.—Except as provided in paragraph
3 (1)(B), the external review process of a plan or
4 issuer under this section shall be conducted under a
5 contract between the plan or issuer and 1 or more
6 qualified external review entities (as defined in para-
7 graph (4)(A)).

8 (3) TERMS AND CONDITIONS OF CONTRACT.—
9 The terms and conditions of a contract under para-
10 graph (2) shall—

11 (A) be consistent with the standards the
12 appropriate Secretary shall establish to assure
13 there is no real or apparent conflict of interest
14 in the conduct of external review activities; and

15 (B) provide that the costs of the external
16 review process shall be borne by the plan or
17 issuer.

18 Subparagraph (B) shall not be construed as apply-
19 ing to the imposition of a filing fee under subsection
20 (b)(2)(A)(iv) or costs incurred by the participant,
21 beneficiary, or enrollee (or authorized representative)
22 or treating health care professional (if any) in sup-
23 port of the review, including the provision of addi-
24 tional evidence or information.

25 (4) QUALIFICATIONS.—

1 (A) IN GENERAL.—In this section, the
2 term “qualified external review entity” means,
3 in relation to a plan or issuer, an entity that is
4 initially certified (and periodically recertified)
5 under subparagraph (C) as meeting the fol-
6 lowing requirements:

7 (i) The entity has (directly or through
8 contracts or other arrangements) sufficient
9 medical, legal, and other expertise and suf-
10 ficient staffing to carry out duties of a
11 qualified external review entity under this
12 section on a timely basis, including making
13 determinations under subsection (b)(2)(A)
14 and providing for independent medical re-
15 views under subsection (d).

16 (ii) The entity is not a plan or issuer
17 or an affiliate or a subsidiary of a plan or
18 issuer, and is not an affiliate or subsidiary
19 of a professional or trade association of
20 plans or issuers or of health care providers.

21 (iii) The entity has provided assur-
22 ances that it will conduct external review
23 activities consistent with the applicable re-
24 quirements of this section and standards
25 specified in subparagraph (C), including

1 that it will not conduct any external review
2 activities in a case unless the independence
3 requirements of subparagraph (B) are met
4 with respect to the case.

5 (iv) The entity has provided assur-
6 ances that it will provide information in a
7 timely manner under subparagraph (D).

8 (v) The entity meets such other re-
9 quirements as the appropriate Secretary
10 provides by regulation.

11 (B) INDEPENDENCE REQUIREMENTS.—

12 (i) IN GENERAL.—Subject to clause
13 (ii), an entity meets the independence re-
14 quirements of this subparagraph with re-
15 spect to any case if the entity—

16 (I) is not a related party (as de-
17 fined in subsection (g)(7));

18 (II) does not have a material fa-
19 milial, financial, or professional rela-
20 tionship with such a party; and

21 (III) does not otherwise have a
22 conflict of interest with such a party
23 (as determined under regulations).

24 (ii) EXCEPTION FOR REASONABLE
25 COMPENSATION.—Nothing in clause (i)

1 shall be construed to prohibit receipt by a
2 qualified external review entity of com-
3 pensation from a plan or issuer for the
4 conduct of external review activities under
5 this section if the compensation is provided
6 consistent with clause (iii).

7 (iii) LIMITATIONS ON ENTITY COM-
8 PENSATION.—Compensation provided by a
9 plan or issuer to a qualified external review
10 entity in connection with reviews under
11 this section shall—

12 (I) not exceed a reasonable level;

13 and

14 (II) not be contingent on any de-
15 cision rendered by the entity or by
16 any independent medical reviewer.

17 (C) CERTIFICATION AND RECERTIFICATION
18 PROCESS.—

19 (i) IN GENERAL.—The initial certifi-
20 cation and recertification of a qualified ex-
21 ternal review entity shall be made—

22 (I) under a process that is recog-
23 nized or approved by the appropriate
24 Secretary; or

1 (II) by a qualified private stand-
2 ard-setting organization that is ap-
3 proved by the appropriate Secretary
4 under clause (iii).

5 In taking action under subclause (I), the
6 appropriate Secretary shall give deference
7 to entities that are under contract with the
8 Federal Government or with an applicable
9 State authority to perform functions of the
10 type performed by qualified external review
11 entities.

12 (ii) PROCESS.—The appropriate Sec-
13 retary shall not recognize or approve a
14 process under clause (i)(I) unless the proc-
15 ess applies standards (as promulgated in
16 regulations) that ensure that a qualified
17 external review entity—

18 (I) will carry out (and has car-
19 ried out, in the case of recertification)
20 the responsibilities of such an entity
21 in accordance with this section, in-
22 cluding meeting applicable deadlines;

23 (II) will meet (and has met, in
24 the case of recertification) appropriate
25 indicators of fiscal integrity;

1 (III) will maintain (and has
2 maintained, in the case of recertifi-
3 cation) appropriate confidentiality
4 with respect to individually identifi-
5 able health information obtained in
6 the course of conducting external re-
7 view activities; and

8 (IV) in the case of recertification,
9 shall review the matters described in
10 clause (iv).

11 (iii) APPROVAL OF QUALIFIED PRI-
12 VATE STANDARD-SETTING ORGANIZA-
13 TIONS.—For purposes of clause (i)(II), the
14 appropriate Secretary may approve a quali-
15 fied private standard-setting organization
16 if such Secretary finds that the organiza-
17 tion only certifies (or recertifies) external
18 review entities that meet at least the
19 standards required for the certification (or
20 recertification) of external review entities
21 under clause (ii).

22 (iv) CONSIDERATIONS IN RECERTIFI-
23 CATIONS.—In conducting recertifications of
24 a qualified external review entity under
25 this paragraph, the appropriate Secretary

1 or organization conducting the recertifi-
2 cation shall review compliance of the entity
3 with the requirements for conducting ex-
4 ternal review activities under this section,
5 including the following:

6 (I) Provision of information
7 under subparagraph (D).

8 (II) Adherence to applicable
9 deadlines (both by the entity and by
10 independent medical reviewers it re-
11 fers cases to).

12 (III) Compliance with limitations
13 on compensation (with respect to both
14 the entity and independent medical re-
15 viewers it refers cases to).

16 (IV) Compliance with applicable
17 independence requirements.

18 (v) PERIOD OF CERTIFICATION OR RE-
19 CERTIFICATION.—A certification or recer-
20 tification provided under this paragraph
21 shall extend for a period not to exceed 2
22 years.

23 (vi) REVOCATION.—A certification or
24 recertification under this paragraph may
25 be revoked by the appropriate Secretary or

1 by the organization providing such certifi-
2 cation upon a showing of cause.

3 (vii) SUFFICIENT NUMBER OF ENTI-
4 TIES.—The appropriate Secretary shall
5 certify and recertify a number of external
6 review entities which is sufficient to ensure
7 the timely and efficient provision of review
8 services.

9 (D) PROVISION OF INFORMATION.—

10 (i) IN GENERAL.—A qualified external
11 review entity shall provide to the appro-
12 priate Secretary, in such manner and at
13 such times as such Secretary may require,
14 such information (relating to the denials
15 which have been referred to the entity for
16 the conduct of external review under this
17 section) as such Secretary determines ap-
18 propriate to assure compliance with the
19 independence and other requirements of
20 this section to monitor and assess the qual-
21 ity of its external review activities and lack
22 of bias in making determinations. Such in-
23 formation shall include information de-
24 scribed in clause (ii) but shall not include

1 individually identifiable medical informa-
2 tion.

3 (ii) INFORMATION TO BE IN-
4 CLUDED.—The information described in
5 this subclause with respect to an entity is
6 as follows:

7 (I) The number and types of de-
8 nials for which a request for review
9 has been received by the entity.

10 (II) The disposition by the entity
11 of such denials, including the number
12 referred to a independent medical re-
13 viewer and the reasons for such dis-
14 positions (including the application of
15 exclusions), on a plan or issuer-spe-
16 cific basis and on a health care spe-
17 cialty-specific basis.

18 (III) The length of time in mak-
19 ing determinations with respect to
20 such denials.

21 (IV) Updated information on the
22 information required to be submitted
23 as a condition of certification with re-
24 spect to the entity's performance of
25 external review activities.

1 (iii) INFORMATION TO BE PROVIDED
2 TO CERTIFYING ORGANIZATION.—

3 (I) IN GENERAL.—In the case of
4 a qualified external review entity
5 which is certified (or recertified)
6 under this subsection by a qualified
7 private standard-setting organization,
8 at the request of the organization, the
9 entity shall provide the organization
10 with the information provided to the
11 appropriate Secretary under clause
12 (i).

13 (II) ADDITIONAL INFORMA-
14 TION.—Nothing in this subparagraph
15 shall be construed as preventing such
16 an organization from requiring addi-
17 tional information as a condition of
18 certification or recertification of an
19 entity.

20 (iv) USE OF INFORMATION.—Informa-
21 tion provided under this subparagraph may
22 be used by the appropriate Secretary and
23 qualified private standard-setting organiza-
24 tions to conduct oversight of qualified ex-
25 ternal review entities, including recertifi-

1 cation of such entities, and shall be made
 2 available to the public in an appropriate
 3 manner.

4 (E) LIMITATION ON LIABILITY.—No quali-
 5 fied external review entity having a contract
 6 with a plan or issuer, and no person who is em-
 7 ployed by any such entity or who furnishes pro-
 8 fessional services to such entity (including as an
 9 independent medical reviewer), shall be held by
 10 reason of the performance of any duty, func-
 11 tion, or activity required or authorized pursuant
 12 to this section, to be civilly liable under any law
 13 of the United States or of any State (or polit-
 14 ical subdivision thereof) if there was no actual
 15 malice or gross misconduct in the performance
 16 of such duty, function, or activity.

17 **Subtitle B—Access to Care**

18 **SEC. 111. CONSUMER CHOICE OPTION.**

19 (a) IN GENERAL.—If—

20 (1) a health insurance issuer providing health
 21 insurance coverage in connection with a group health
 22 plan offers to enrollees health insurance coverage
 23 which provides for coverage of services only if such
 24 services are furnished through health care profes-
 25 sionals and providers who are members of a network

1 of health care professionals and providers who have
2 entered into a contract with the issuer to provide
3 such services, or

4 (2) a group health plan offers to participants or
5 beneficiaries health benefits which provide for cov-
6 erage of services only if such services are furnished
7 through health care professionals and providers who
8 are members of a network of health care profes-
9 sionals and providers who have entered into a con-
10 tract with the plan to provide such services,

11 then the issuer or plan shall also offer or arrange to be
12 offered to such enrollees, participants, or beneficiaries (at
13 the time of enrollment and during an annual open season
14 as provided under subsection (c)) the option of health in-
15 surance coverage or health benefits which provide for cov-
16 erage of such services which are not furnished through
17 health care professionals and providers who are members
18 of such a network unless such enrollees, participants, or
19 beneficiaries are offered such non-network coverage
20 through another group health plan or through another
21 health insurance issuer in the group market.

22 (b) ADDITIONAL COSTS.—The amount of any addi-
23 tional premium charged by the health insurance issuer or
24 group health plan for the additional cost of the creation
25 and maintenance of the option described in subsection (a)

1 and the amount of any additional cost sharing imposed
2 under such option shall be borne by the enrollee, partici-
3 pant, or beneficiary unless it is paid by the health plan
4 sponsor or group health plan through agreement with the
5 health insurance issuer.

6 (c) OPEN SEASON.—An enrollee, participant, or ben-
7 eficiary, may change to the offering provided under this
8 section only during a time period determined by the health
9 insurance issuer or group health plan. Such time period
10 shall occur at least annually.

11 **SEC. 112. CHOICE OF HEALTH CARE PROFESSIONAL.**

12 (a) PRIMARY CARE.—If a group health plan, or a
13 health insurance issuer that offers health insurance cov-
14 erage, requires or provides for designation by a partici-
15 pant, beneficiary, or enrollee of a participating primary
16 care provider, then the plan or issuer shall permit each
17 participant, beneficiary, and enrollee to designate any par-
18 ticipating primary care provider who is available to accept
19 such individual.

20 (b) SPECIALISTS.—

21 (1) IN GENERAL.—Subject to paragraph (2), a
22 group health plan and a health insurance issuer that
23 offers health insurance coverage shall permit each
24 participant, beneficiary, or enrollee to receive medi-
25 cally necessary or appropriate specialty care, pursu-

1 ant to appropriate referral procedures, from any
2 qualified participating health care professional who
3 is available to accept such individual for such care.

4 (2) LIMITATION.—Paragraph (1) shall not
5 apply to specialty care if the plan or issuer clearly
6 informs participants, beneficiaries, and enrollees of
7 the limitations on choice of participating health care
8 professionals with respect to such care.

9 (3) CONSTRUCTION.—Nothing in this sub-
10 section shall be construed as affecting the applica-
11 tion of section 114 (relating to access to specialty
12 care).

13 **SEC. 113. ACCESS TO EMERGENCY CARE.**

14 (a) COVERAGE OF EMERGENCY SERVICES.—

15 (1) IN GENERAL.—If a group health plan, or
16 health insurance coverage offered by a health insur-
17 ance issuer, provides or covers any benefits with re-
18 spect to services in an emergency department of a
19 hospital, the plan or issuer shall cover emergency
20 services (as defined in paragraph (2)(B))—

21 (A) without the need for any prior author-
22 ization determination;

23 (B) whether the health care provider fur-
24 nishing such services is a participating provider
25 with respect to such services;

1 (C) in a manner so that, if such services
2 are provided to a participant, beneficiary, or
3 enrollee—

4 (i) by a nonparticipating health care
5 provider with or without prior authoriza-
6 tion, or

7 (ii) by a participating health care pro-
8 vider without prior authorization,

9 the participant, beneficiary, or enrollee is not
10 liable for amounts that exceed the amounts of
11 liability that would be incurred if the services
12 were provided by a participating health care
13 provider with prior authorization; and

14 (D) without regard to any other term or
15 condition of such coverage (other than exclusion
16 or coordination of benefits, or an affiliation or
17 waiting period, permitted under section 2701 of
18 the Public Health Service Act, section 701 of
19 the Employee Retirement Income Security Act
20 of 1974, or section 9801 of the Internal Rev-
21 enue Code of 1986, and other than applicable
22 cost-sharing).

23 (2) DEFINITIONS.—In this section:

24 (A) EMERGENCY MEDICAL CONDITION.—

25 The term “emergency medical condition” means

1 a medical condition manifesting itself by acute
2 symptoms of sufficient severity (including se-
3 vere pain) such that a prudent layperson, who
4 possesses an average knowledge of health and
5 medicine, could reasonably expect the absence
6 of immediate medical attention to result in a
7 condition described in clause (i), (ii), or (iii) of
8 section 1867(e)(1)(A) of the Social Security
9 Act.

10 (B) EMERGENCY SERVICES.—The term
11 “emergency services” means, with respect to an
12 emergency medical condition—

13 (i) a medical screening examination
14 (as required under section 1867 of the So-
15 cial Security Act) that is within the capa-
16 bility of the emergency department of a
17 hospital, including ancillary services rou-
18 tinely available to the emergency depart-
19 ment to evaluate such emergency medical
20 condition, and

21 (ii) within the capabilities of the staff
22 and facilities available at the hospital, such
23 further medical examination and treatment
24 as are required under section 1867 of such
25 Act to stabilize the patient.

1 (C) STABILIZE.—The term “to stabilize”,
2 with respect to an emergency medical condition
3 (as defined in subparagraph (A)), has the
4 meaning give in section 1867(e)(3) of the Social
5 Security Act (42 U.S.C. 1395dd(e)(3)).

6 (b) REIMBURSEMENT FOR MAINTENANCE CARE AND
7 POST-STABILIZATION CARE.—A group health plan, and
8 health insurance coverage offered by a health insurance
9 issuer, must provide reimbursement for maintenance care
10 and post-stabilization care in accordance with the require-
11 ments of section 1852(d)(2) of the Social Security Act (42
12 U.S.C. 1395w–22(d)(2)). Such reimbursement shall be
13 provided in a manner consistent with subsection (a)(1)(C).

14 (c) COVERAGE OF EMERGENCY AMBULANCE SERV-
15 ICES.—

16 (1) IN GENERAL.—If a group health plan, or
17 health insurance coverage provided by a health in-
18 surance issuer, provides any benefits with respect to
19 ambulance services and emergency services, the plan
20 or issuer shall cover emergency ambulance services
21 (as defined in paragraph (2)) furnished under the
22 plan or coverage under the same terms and condi-
23 tions under subparagraphs (A) through (D) of sub-
24 section (a)(1) under which coverage is provided for
25 emergency services.

1 (2) EMERGENCY AMBULANCE SERVICES.—For
2 purposes of this subsection, the term “emergency
3 ambulance services” means ambulance services (as
4 defined for purposes of section 1861(s)(7) of the So-
5 cial Security Act) furnished to transport an indi-
6 vidual who has an emergency medical condition (as
7 defined in subsection (a)(2)(A)) to a hospital for the
8 receipt of emergency services (as defined in sub-
9 section (a)(2)(B)) in a case in which the emergency
10 services are covered under the plan or coverage pur-
11 suant to subsection (a)(1) and a prudent layperson,
12 with an average knowledge of health and medicine,
13 could reasonably expect that the absence of such
14 transport would result in placing the health of the
15 individual in serious jeopardy, serious impairment of
16 bodily function, or serious dysfunction of any bodily
17 organ or part.

18 **SEC. 114. TIMELY ACCESS TO SPECIALISTS.**

19 (a) TIMELY ACCESS.—

20 (1) IN GENERAL.—A group health plan or
21 health insurance issuer offering health insurance
22 coverage shall ensure that participants, beneficiaries,
23 and enrollees receive timely access to specialists who
24 are appropriate to the condition of, and accessible
25 to, the participant, beneficiary, or enrollee, when

1 such specialty care is a covered benefit under the
2 plan or coverage.

3 (2) RULE OF CONSTRUCTION.—Nothing in
4 paragraph (1) shall be construed—

5 (A) to require the coverage under a group
6 health plan or health insurance coverage of ben-
7 efits or services;

8 (B) to prohibit a plan or issuer from in-
9 cluding providers in the network only to the ex-
10 tent necessary to meet the needs of the plan's
11 or issuer's participants, beneficiaries, or enroll-
12 ees; or

13 (C) to override any State licensure or
14 scope-of-practice law.

15 (3) ACCESS TO CERTAIN PROVIDERS.—

16 (A) IN GENERAL.—With respect to spe-
17 cialty care under this section, if a participating
18 specialist is not available and qualified to pro-
19 vide such care to the participant, beneficiary, or
20 enrollee, the plan or issuer shall provide for cov-
21 erage of such care by a nonparticipating spe-
22 cialist.

23 (B) TREATMENT OF NONPARTICIPATING
24 PROVIDERS.—If a participant, beneficiary, or
25 enrollee receives care from a nonparticipating

1 specialist pursuant to subparagraph (A), such
2 specialty care shall be provided at no additional
3 cost to the participant, beneficiary, or enrollee
4 beyond what the participant, beneficiary, or en-
5 rollee would otherwise pay for such specialty
6 care if provided by a participating specialist.

7 (b) REFERRALS.—

8 (1) AUTHORIZATION.—A group health plan or
9 health insurance issuer may require an authorization
10 in order to obtain coverage for specialty services
11 under this section. Any such authorization—

12 (A) shall be for an appropriate duration of
13 time or number of referrals; and

14 (B) may not be refused solely because the
15 authorization involves services of a nonpartici-
16 pating specialist (described in subsection
17 (a)(3)).

18 (2) REFERRALS FOR ONGOING SPECIAL CONDI-
19 TIONS.—

20 (A) IN GENERAL.—A group health plan or
21 health insurance issuer shall permit a partici-
22 pant, beneficiary, or enrollee who has an ongo-
23 ing special condition (as defined in subpara-
24 graph (B)) to receive a referral to a specialist
25 for the treatment of such condition and such

1 specialist may authorize such referrals, proce-
2 dures, tests, and other medical services with re-
3 spect to such condition, or coordinate the care
4 for such condition, subject to the terms of a
5 treatment plan (if any) referred to in subsection
6 (c) with respect to the condition.

7 (B) ONGOING SPECIAL CONDITION DE-
8 FINED.—In this subsection, the term “ongoing
9 special condition” means a condition or disease
10 that—

11 (i) is life-threatening, degenerative,
12 potentially disabling, or congenital; and

13 (ii) requires specialized medical care
14 over a prolonged period of time.

15 (c) TREATMENT PLANS.—

16 (1) IN GENERAL.—A group health plan or
17 health insurance issuer may require that the spe-
18 cialty care be provided—

19 (A) pursuant to a treatment plan, but only
20 if the treatment plan—

21 (i) is developed by the specialist, in
22 consultation with the case manager or pri-
23 mary care provider, and the participant,
24 beneficiary, or enrollee, and

1 (ii) is approved by the plan or issuer
2 in a timely manner, if the plan or issuer
3 requires such approval; and

4 (B) in accordance with applicable quality
5 assurance and utilization review standards of
6 the plan or issuer.

7 (2) NOTIFICATION.—Nothing in paragraph (1)
8 shall be construed as prohibiting a plan or issuer
9 from requiring the specialist to provide the plan or
10 issuer with regular updates on the specialty care
11 provided, as well as all other reasonably necessary
12 medical information.

13 (d) SPECIALIST DEFINED.—For purposes of this sec-
14 tion, the term “specialist” means, with respect to the con-
15 dition of the participant, beneficiary, or enrollee, a health
16 care professional, facility, or center that has adequate ex-
17 pertise through appropriate training and experience (in-
18 cluding, in the case of a child, appropriate pediatric exper-
19 tise) to provide high quality care in treating the condition.

20 **SEC. 115. PATIENT ACCESS TO OBSTETRIC AND GYNECO-**
21 **LOGICAL CARE.**

22 (a) GENERAL RIGHTS.—

23 (1) DIRECT ACCESS.—A group health plan, or
24 health insurance issuer offering health insurance
25 coverage, described in subsection (b) may not re-

1 quire authorization or referral by the plan, issuer, or
2 any person (including a primary care provider de-
3 scribed in subsection (b)(2)) in the case of a female
4 participant, beneficiary, or enrollee who seeks cov-
5 erage for obstetrical or gynecological care provided
6 by a participating health care professional who spe-
7 cializes in obstetrics or gynecology.

8 (2) OBSTETRICAL AND GYNECOLOGICAL
9 CARE.—A group health plan or health insurance
10 issuer described in subsection (b) shall treat the pro-
11 vision of obstetrical and gynecological care, and the
12 ordering of related obstetrical and gynecological
13 items and services, pursuant to the direct access de-
14 scribed under paragraph (1), by a participating
15 health care professional who specializes in obstetrics
16 or gynecology as the authorization of the primary
17 care provider.

18 (b) APPLICATION OF SECTION.—A group health plan,
19 or health insurance issuer offering health insurance cov-
20 erage, described in this subsection is a group health plan
21 or coverage that—

22 (1) provides coverage for obstetric or
23 gynecologic care; and

1 (2) requires the designation by a participant,
2 beneficiary, or enrollee of a participating primary
3 care provider.

4 (c) CONSTRUCTION.—Nothing in subsection (a) shall
5 be construed to—

6 (1) waive any exclusions of coverage under the
7 terms and conditions of the plan or health insurance
8 coverage with respect to coverage of obstetrical or
9 gynecological care; or

10 (2) preclude the group health plan or health in-
11 surance issuer involved from requiring that the ob-
12 stetrical or gynecological provider notify the primary
13 health care professional or the plan or issuer of
14 treatment decisions.

15 **SEC. 116. ACCESS TO PEDIATRIC CARE.**

16 (a) PEDIATRIC CARE.—In the case of a person who
17 has a child who is a participant, beneficiary, or enrollee
18 under a group health plan, or health insurance coverage
19 offered by a health insurance issuer, if the plan or issuer
20 requires or provides for the designation of a participating
21 primary care provider for the child, the plan or issuer shall
22 permit such person to designate a physician (allopathic or
23 osteopathic) who specializes in pediatrics as the child's pri-
24 mary care provider if such provider participates in the net-
25 work of the plan or issuer.

1 (b) CONSTRUCTION.—Nothing in subsection (a) shall
2 be construed to waive any exclusions of coverage under
3 the terms and conditions of the plan or health insurance
4 coverage with respect to coverage of pediatric care.

5 **SEC. 117. CONTINUITY OF CARE.**

6 (a) TERMINATION OF PROVIDER.—

7 (1) IN GENERAL.—If—

8 (A) a contract between a group health
9 plan, or a health insurance issuer offering
10 health insurance coverage, and a treating health
11 care provider is terminated (as defined in para-
12 graph (e)(4)), or

13 (B) benefits or coverage provided by a
14 health care provider are terminated because of
15 a change in the terms of provider participation
16 in such plan or coverage,
17 the plan or issuer shall meet the requirements of
18 paragraph (3) with respect to each continuing care
19 patient.

20 (2) TREATMENT OF TERMINATION OF CON-
21 TRACT WITH HEALTH INSURANCE ISSUER.—If a
22 contract for the provision of health insurance cov-
23 erage between a group health plan and a health in-
24 surance issuer is terminated and, as a result of such
25 termination, coverage of services of a health care

1 provider is terminated with respect to an individual,
2 the provisions of paragraph (1) (and the succeeding
3 provisions of this section) shall apply under the plan
4 in the same manner as if there had been a contract
5 between the plan and the provider that had been ter-
6 minated, but only with respect to benefits that are
7 covered under the plan after the contract termi-
8 nation.

9 (3) REQUIREMENTS.—The requirements of this
10 paragraph are that the plan or issuer—

11 (A) notify the continuing care patient in-
12 volved, or arrange to have the patient notified
13 pursuant to subsection (d)(2), on a timely basis
14 of the termination described in paragraph (1)
15 (or paragraph (2), if applicable) and the right
16 to elect continued transitional care from the
17 provider under this section;

18 (B) provide the patient with an oppor-
19 tunity to notify the plan or issuer of the pa-
20 tient's need for transitional care; and

21 (C) subject to subsection (c), permit the
22 patient to elect to continue to be covered with
23 respect to the course of treatment by such pro-
24 vider with the provider's consent during a tran-

1 sitional period (as provided for under subsection
2 (b)).

3 (4) CONTINUING CARE PATIENT.—For purposes
4 of this section, the term “continuing care patient”
5 means a participant, beneficiary, or enrollee who—

6 (A) is undergoing a course of treatment
7 for a serious and complex condition from the
8 provider at the time the plan or issuer receives
9 or provides notice of provider, benefit, or cov-
10 erage termination described in paragraph (1)
11 (or paragraph (2), if applicable);

12 (B) is undergoing a course of institutional
13 or inpatient care from the provider at the time
14 of such notice;

15 (C) is scheduled to undergo non-elective
16 surgery from the provider at the time of such
17 notice;

18 (D) is pregnant and undergoing a course
19 of treatment for the pregnancy from the pro-
20 vider at the time of such notice; or

21 (E) is or was determined to be terminally
22 ill (as determined under section 1861(dd)(3)(A)
23 of the Social Security Act) at the time of such
24 notice, but only with respect to a provider that

1 was treating the terminal illness before the date
2 of such notice.

3 (b) TRANSITIONAL PERIODS.—

4 (1) SERIOUS AND COMPLEX CONDITIONS.—The
5 transitional period under this subsection with re-
6 spect to a continuing care patient described in sub-
7 section (a)(4)(A) shall extend for up to 90 days (as
8 determined by the treating health care professional)
9 from the date of the notice described in subsection
10 (a)(3)(A).

11 (2) INSTITUTIONAL OR INPATIENT CARE.—The
12 transitional period under this subsection for a con-
13 tinuing care patient described in subsection
14 (a)(4)(B) shall extend until the earlier of—

15 (A) the expiration of the 90-day period be-
16 ginning on the date on which the notice under
17 subsection (a)(3)(A) is provided; or

18 (B) the date of discharge of the patient
19 from such care or the termination of the period
20 of institutionalization, or, if later, the date of
21 completion of reasonable follow-up care.

22 (3) SCHEDULED NON-ELECTIVE SURGERY.—
23 The transitional period under this subsection for a
24 continuing care patient described in subsection
25 (a)(4)(C) shall extend until the completion of the

1 surgery involved and post-surgical follow-up care re-
2 lating to the surgery and occurring within 90 days
3 after the date of the surgery.

4 (4) PREGNANCY.—The transitional period
5 under this subsection for a continuing care patient
6 described in subsection (a)(4)(D) shall extend
7 through the provision of post-partum care directly
8 related to the delivery.

9 (5) TERMINAL ILLNESS.—The transitional pe-
10 riod under this subsection for a continuing care pa-
11 tient described in subsection (a)(4)(E) shall extend
12 for the remainder of the patient's life for care that
13 is directly related to the treatment of the terminal
14 illness or its medical manifestations.

15 (c) PERMISSIBLE TERMS AND CONDITIONS.—A
16 group health plan or health insurance issuer may condi-
17 tion coverage of continued treatment by a provider under
18 this section upon the provider agreeing to the following
19 terms and conditions:

20 (1) The treating health care provider agrees to
21 accept reimbursement from the plan or issuer and
22 continuing care patient involved (with respect to
23 cost-sharing) at the rates applicable prior to the
24 start of the transitional period as payment in full
25 (or, in the case described in subsection (a)(2), at the

1 rates applicable under the replacement plan or cov-
2 erage after the date of the termination of the con-
3 tract with the group health plan or health insurance
4 issuer) and not to impose cost-sharing with respect
5 to the patient in an amount that would exceed the
6 cost-sharing that could have been imposed if the
7 contract referred to in subsection (a)(1) had not
8 been terminated.

9 (2) The treating health care provider agrees to
10 adhere to the quality assurance standards of the
11 plan or issuer responsible for payment under para-
12 graph (1) and to provide to such plan or issuer nec-
13 essary medical information related to the care pro-
14 vided.

15 (3) The treating health care provider agrees
16 otherwise to adhere to such plan's or issuer's policies
17 and procedures, including procedures regarding re-
18 ferrals and obtaining prior authorization and pro-
19 viding services pursuant to a treatment plan (if any)
20 approved by the plan or issuer.

21 (d) RULES OF CONSTRUCTION.—Nothing in this sec-
22 tion shall be construed—

23 (1) to require the coverage of benefits which
24 would not have been covered if the provider involved
25 remained a participating provider; or

1 (2) with respect to the termination of a con-
 2 tract under subsection (a) to prevent a group health
 3 plan or health insurance issuer from requiring that
 4 the health care provider—

5 (A) notify participants, beneficiaries, or en-
 6 rollees of their rights under this section; or

7 (B) provide the plan or issuer with the
 8 name of each participant, beneficiary, or en-
 9 rollee who the provider believes is a continuing
 10 care patient.

11 (e) DEFINITIONS.—In this section:

12 (1) CONTRACT.—The term “contract” includes,
 13 with respect to a plan or issuer and a treating
 14 health care provider, a contract between such plan
 15 or issuer and an organized network of providers that
 16 includes the treating health care provider, and (in
 17 the case of such a contract) the contract between the
 18 treating health care provider and the organized net-
 19 work.

20 (2) HEALTH CARE PROVIDER.—The term
 21 “health care provider” or “provider” means—

22 (A) any individual who is engaged in the
 23 delivery of health care services in a State and
 24 who is required by State law or regulation to be

1 licensed or certified by the State to engage in
2 the delivery of such services in the State; and

3 (B) any entity that is engaged in the deliv-
4 ery of health care services in a State and that,
5 if it is required by State law or regulation to be
6 licensed or certified by the State to engage in
7 the delivery of such services in the State, is so
8 licensed.

9 (3) SERIOUS AND COMPLEX CONDITION.—The
10 term “serious and complex condition” means, with
11 respect to a participant, beneficiary, or enrollee
12 under the plan or coverage—

13 (A) in the case of an acute illness, a condi-
14 tion that is serious enough to require special-
15 ized medical treatment to avoid the reasonable
16 possibility of death or permanent harm; or

17 (B) in the case of a chronic illness or con-
18 dition, is an ongoing special condition (as de-
19 fined in section 114(b)(2)(B)).

20 (4) TERMINATED.—The term “terminated” in-
21 cludes, with respect to a contract, the expiration or
22 nonrenewal of the contract, but does not include a
23 termination of the contract for failure to meet appli-
24 cable quality standards or for fraud.

1 **SEC. 118. ACCESS TO NEEDED PRESCRIPTION DRUGS.**

2 (a) IN GENERAL.—To the extent that a group health
3 plan, or health insurance coverage offered by a health in-
4 surance issuer, provides coverage for benefits with respect
5 to prescription drugs, and limits such coverage to drugs
6 included in a formulary, the plan or issuer shall—

7 (1) ensure the participation of physicians and
8 pharmacists in developing and reviewing such for-
9 mulary;

10 (2) provide for disclosure of the formulary to
11 providers; and

12 (3) in accordance with the applicable quality as-
13 surance and utilization review standards of the plan
14 or issuer, provide for exceptions from the formulary
15 limitation when a non-formulary alternative is medi-
16 cally necessary and appropriate and, in the case of
17 such an exception, apply the same cost-sharing re-
18 quirements that would have applied in the case of a
19 drug covered under the formulary.

20 (b) COVERAGE OF APPROVED DRUGS AND MEDICAL
21 DEVICES.—

22 (1) IN GENERAL.—A group health plan (or
23 health insurance coverage offered in connection with
24 such a plan) that provides any coverage of prescrip-
25 tion drugs or medical devices shall not deny coverage

1 of such a drug or device on the basis that the use
2 is investigational, if the use—

3 (A) in the case of a prescription drug—

4 (i) is included in the labeling author-
5 ized by the application in effect for the
6 drug pursuant to subsection (b) or (j) of
7 section 505 of the Federal Food, Drug,
8 and Cosmetic Act, without regard to any
9 postmarketing requirements that may
10 apply under such Act; or

11 (ii) is included in the labeling author-
12 ized by the application in effect for the
13 drug under section 351 of the Public
14 Health Service Act, without regard to any
15 postmarketing requirements that may
16 apply pursuant to such section; or

17 (B) in the case of a medical device, is in-
18 cluded in the labeling authorized by a regula-
19 tion under subsection (d) or (3) of section 513
20 of the Federal Food, Drug, and Cosmetic Act,
21 an order under subsection (f) of such section, or
22 an application approved under section 515 of
23 such Act, without regard to any postmarketing
24 requirements that may apply under such Act.

1 (2) CONSTRUCTION.—Nothing in this sub-
2 section shall be construed as requiring a group
3 health plan (or health insurance coverage offered in
4 connection with such a plan) to provide any coverage
5 of prescription drugs or medical devices.

6 **SEC. 119. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
7 **APPROVED CLINICAL TRIALS.**

8 (a) COVERAGE.—

9 (1) IN GENERAL.—If a group health plan, or
10 health insurance issuer that is providing health in-
11 surance coverage, provides coverage to a qualified in-
12 dividual (as defined in subsection (b)), the plan or
13 issuer—

14 (A) may not deny the individual participa-
15 tion in the clinical trial referred to in subsection
16 (b)(2);

17 (B) subject to subsection (c), may not deny
18 (or limit or impose additional conditions on) the
19 coverage of routine patient costs for items and
20 services furnished in connection with participa-
21 tion in the trial; and

22 (C) may not discriminate against the indi-
23 vidual on the basis of the enrollee's participa-
24 tion in such trial.

1 (2) EXCLUSION OF CERTAIN COSTS.—For pur-
2 poses of paragraph (1)(B), routine patient costs do
3 not include the cost of the tests or measurements
4 conducted primarily for the purpose of the clinical
5 trial involved.

6 (3) USE OF IN-NETWORK PROVIDERS.—If one
7 or more participating providers is participating in a
8 clinical trial, nothing in paragraph (1) shall be con-
9 strued as preventing a plan or issuer from requiring
10 that a qualified individual participate in the trial
11 through such a participating provider if the provider
12 will accept the individual as a participant in the
13 trial.

14 (b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
15 poses of subsection (a), the term “qualified individual”
16 means an individual who is a participant or beneficiary
17 in a group health plan, or who is an enrollee under health
18 insurance coverage, and who meets the following condi-
19 tions:

20 (1)(A) The individual has a life-threatening or
21 serious illness for which no standard treatment is ef-
22 fective.

23 (B) The individual is eligible to participate in
24 an approved clinical trial according to the trial pro-
25 tocol with respect to treatment of such illness.

1 (C) The individual's participation in the trial
2 offers meaningful potential for significant clinical
3 benefit for the individual.

4 (2) Either—

5 (A) the referring physician is a partici-
6 pating health care professional and has con-
7 cluded that the individual's participation in
8 such trial would be appropriate based upon the
9 individual meeting the conditions described in
10 paragraph (1); or

11 (B) the participant, beneficiary, or enrollee
12 provides medical and scientific information es-
13 tablishing that the individual's participation in
14 such trial would be appropriate based upon the
15 individual meeting the conditions described in
16 paragraph (1).

17 (c) PAYMENT.—

18 (1) IN GENERAL.—Under this section a group
19 health plan or health insurance issuer shall provide
20 for payment for routine patient costs described in
21 subsection (a)(2) but is not required to pay for costs
22 of items and services that are reasonably expected
23 (as determined by the appropriate Secretary) to be
24 paid for by the sponsors of an approved clinical trial.

1 (2) PAYMENT RATE.—In the case of covered
2 items and services provided by—

3 (A) a participating provider, the payment
4 rate shall be at the agreed upon rate; or

5 (B) a nonparticipating provider, the pay-
6 ment rate shall be at the rate the plan or issuer
7 would normally pay for comparable services
8 under subparagraph (A).

9 (d) APPROVED CLINICAL TRIAL DEFINED.—

10 (1) IN GENERAL.—In this section, the term
11 “approved clinical trial” means a clinical research
12 study or clinical investigation approved and funded
13 (which may include funding through in-kind con-
14 tributions) by one or more of the following:

15 (A) The National Institutes of Health.

16 (B) A cooperative group or center of the
17 National Institutes of Health.

18 (C) The Food and Drug Administration.

19 (D) Either of the following if the condi-
20 tions described in paragraph (2) are met:

21 (i) The Department of Veterans Af-
22 fairs.

23 (ii) The Department of Defense.

24 (2) CONDITIONS FOR DEPARTMENTS.—The
25 conditions described in this paragraph, for a study

or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the appropriate Secretary determines—

(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; and

(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan’s or issuer’s coverage with respect to clinical trials.

SEC. 120. REQUIRED COVERAGE FOR MINIMUM HOSPITAL STAY FOR MASTECTOMIES AND LYMPH NODE DISSECTIONS FOR THE TREATMENT OF BREAST CANCER AND COVERAGE FOR SECONDARY CONSULTATIONS.

(a) INPATIENT CARE.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer providing health insurance coverage, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physi-

1 cian, in consultation with the patient, to be medi-
2 cally necessary and appropriate following—

3 (A) a mastectomy;

4 (B) a lumpectomy; or

5 (C) a lymph node dissection for the treat-
6 ment of breast cancer.

7 (2) EXCEPTION.—Nothing in this section shall
8 be construed as requiring the provision of inpatient
9 coverage if the attending physician and patient de-
10 termine that a shorter period of hospital stay is
11 medically appropriate.

12 (b) PROHIBITION ON CERTAIN MODIFICATIONS.—In
13 implementing the requirements of this section, a group
14 health plan, and a health insurance issuer providing health
15 insurance coverage, may not modify the terms and condi-
16 tions of coverage based on the determination by a partici-
17 pant, beneficiary, or enrollee to request less than the min-
18 imum coverage required under subsection (a).

19 (c) SECONDARY CONSULTATIONS.—

20 (1) IN GENERAL.—A group health plan, and a
21 health insurance issuer providing health insurance
22 coverage, that provides coverage with respect to
23 medical and surgical services provided in relation to
24 the diagnosis and treatment of cancer shall ensure
25 that full coverage is provided for secondary consulta-

1 tions by specialists in the appropriate medical fields
2 (including pathology, radiology, and oncology) to
3 confirm or refute such diagnosis. Such plan or issuer
4 shall ensure that full coverage is provided for such
5 secondary consultation whether such consultation is
6 based on a positive or negative initial diagnosis. In
7 any case in which the attending physician certifies in
8 writing that services necessary for such a secondary
9 consultation are not sufficiently available from spe-
10 cialists operating under the plan or coverage with re-
11 spect to whose services coverage is otherwise pro-
12 vided under such plan or by such issuer, such plan
13 or issuer shall ensure that coverage is provided with
14 respect to the services necessary for the secondary
15 consultation with any other specialist selected by the
16 attending physician for such purpose at no addi-
17 tional cost to the individual beyond that which the
18 individual would have paid if the specialist was par-
19 ticipating in the network of the plan or issuer.

20 (2) EXCEPTION.—Nothing in paragraph (1)
21 shall be construed as requiring the provision of sec-
22 ondary consultations where the patient determines
23 not to seek such a consultation.

1 (d) PROHIBITION ON PENALTIES OR INCENTIVES.—

2 A group health plan, and a health insurance issuer pro-
3 viding health insurance coverage, may not—

4 (1) penalize or otherwise reduce or limit the re-
5 imbursement of a provider or specialist because the
6 provider or specialist provided care to a participant,
7 beneficiary, or enrollee in accordance with this sec-
8 tion;

9 (2) provide financial or other incentives to a
10 physician or specialist to induce the physician or
11 specialist to keep the length of inpatient stays of pa-
12 tients following a mastectomy, lumpectomy, or a
13 lymph node dissection for the treatment of breast
14 cancer below certain limits or to limit referrals for
15 secondary consultations; or

16 (3) provide financial or other incentives to a
17 physician or specialist to induce the physician or
18 specialist to refrain from referring a participant,
19 beneficiary, or enrollee for a secondary consultation
20 that would otherwise be covered by the plan or cov-
21 erage involved under subsection (c).

22 **Subtitle C—Access to Information**

23 **SEC. 121. PATIENT ACCESS TO INFORMATION.**

24 (a) REQUIREMENT—

25 (1) DISCLOSURE.—

1 (A) IN GENERAL.—A group health plan,
2 and a health insurance issuer that provides cov-
3 erage in connection with health insurance cov-
4 erage, shall provide for the disclosure to partici-
5 pants, beneficiaries, and enrollees—

6 (i) of the information described in
7 subsection (b) at the time of the initial en-
8 rollment of the participant, beneficiary, or
9 enrollee under the plan or coverage;

10 (ii) of such information on an annual
11 basis—

12 (I) in conjunction with the elec-
13 tion period of the plan or coverage if
14 the plan or coverage has such an elec-
15 tion period; or

16 (II) in the case of a plan or cov-
17 erage that does not have an election
18 period, in conjunction with the begin-
19 ning of the plan or coverage year; and

20 (iii) of information relating to any
21 material reduction to the benefits or infor-
22 mation described in such subsection or
23 subsection (c), in the form of a notice pro-
24 vided not later than 30 days before the
25 date on which the reduction takes effect.

1 (B) PARTICIPANTS, BENEFICIARIES, AND
2 ENROLLEES.—The disclosure required under
3 subparagraph (A) shall be provided—

4 (i) jointly to each participant, bene-
5 ficiary, and enrollee who reside at the same
6 address; or

7 (ii) in the case of a beneficiary or en-
8 rollee who does not reside at the same ad-
9 dress as the participant or another en-
10 rollee, separately to the participant or
11 other enrollees and such beneficiary or en-
12 rollee.

13 (2) PROVISION OF INFORMATION.—Information
14 shall be provided to participants, beneficiaries, and
15 enrollees under this section at the last known ad-
16 dress maintained by the plan or issuer with respect
17 to such participants, beneficiaries, or enrollees, to
18 the extent that such information is provided to par-
19 ticipants, beneficiaries, or enrollees via the United
20 States Postal Service or other private delivery serv-
21 ice.

22 (b) REQUIRED INFORMATION.—The informational
23 materials to be distributed under this section shall include
24 for each option available under the group health plan or
25 health insurance coverage the following:

1 (1) BENEFITS.—A description of the covered
2 benefits, including—

3 (A) any in- and out-of-network benefits;

4 (B) specific preventive services covered
5 under the plan or coverage if such services are
6 covered;

7 (C) any specific exclusions or express limi-
8 tations of benefits described in section
9 104(b)(3)(C);

10 (D) any other benefit limitations, including
11 any annual or lifetime benefit limits and any
12 monetary limits or limits on the number of vis-
13 its, days, or services, and any specific coverage
14 exclusions; and

15 (E) any definition of medical necessity
16 used in making coverage determinations by the
17 plan, issuer, or claims administrator.

18 (2) COST SHARING.—A description of any cost-
19 sharing requirements, including—

20 (A) any premiums, deductibles, coinsur-
21 ance, copayment amounts, and liability for bal-
22 ance billing, for which the participant, bene-
23 ficiary, or enrollee will be responsible under
24 each option available under the plan;

1 (B) any maximum out-of-pocket expense
2 for which the participant, beneficiary, or en-
3 rollee may be liable;

4 (C) any cost-sharing requirements for out-
5 of-network benefits or services received from
6 nonparticipating providers; and

7 (D) any additional cost-sharing or charges
8 for benefits and services that are furnished
9 without meeting applicable plan or coverage re-
10 quirements, such as prior authorization or
11 precertification.

12 (3) SERVICE AREA.—A description of the plan
13 or issuer's service area, including the provision of
14 any out-of-area coverage.

15 (4) PARTICIPATING PROVIDERS.—A directory of
16 participating providers (to the extent a plan or
17 issuer provides coverage through a network of pro-
18 viders) that includes, at a minimum, the name, ad-
19 dress, and telephone number of each participating
20 provider, and information about how to inquire
21 whether a participating provider is currently accept-
22 ing new patients.

23 (5) CHOICE OF PRIMARY CARE PROVIDER.—A
24 description of any requirements and procedures to
25 be used by participants, beneficiaries, and enrollees

1 in selecting, accessing, or changing their primary
2 care provider, including providers both within and
3 outside of the network (if the plan or issuer permits
4 out-of-network services), and the right to select a pe-
5 diatrician as a primary care provider under section
6 116 for a participant, beneficiary, or enrollee who is
7 a child if such section applies.

8 (6) PREAUTHORIZATION REQUIREMENTS.—A
9 description of the requirements and procedures to be
10 used to obtain preauthorization for health services,
11 if such preauthorization is required.

12 (7) EXPERIMENTAL AND INVESTIGATIONAL
13 TREATMENTS.—A description of the process for de-
14 termining whether a particular item, service, or
15 treatment is considered experimental or investiga-
16 tional, and the circumstances under which such
17 treatments are covered by the plan or issuer.

18 (8) SPECIALTY CARE.—A description of the re-
19 quirements and procedures to be used by partici-
20 pants, beneficiaries, and enrollees in accessing spe-
21 cialty care and obtaining referrals to participating
22 and nonparticipating specialists, including any limi-
23 tations on choice of health care professionals re-
24 ferred to in section 112(b)(2) and the right to timely

1 access to specialists care under section 114 if such
2 section applies.

3 (9) CLINICAL TRIALS.—A description the cir-
4 cumstances and conditions under which participation
5 in clinical trials is covered under the terms and con-
6 ditions of the plan or coverage, and the right to ob-
7 tain coverage for approved clinical trials under sec-
8 tion 119 if such section applies.

9 (10) PRESCRIPTION DRUGS.—To the extent the
10 plan or issuer provides coverage for prescription
11 drugs, a statement of whether such coverage is lim-
12 ited to drugs included in a formulary, a description
13 of any provisions and cost-sharing required for ob-
14 taining on- and off-formulary medications, and a de-
15 scription of the rights of participants, beneficiaries,
16 and enrollees in obtaining access to access to pre-
17 scription drugs under section 118 if such section ap-
18 plies.

19 (11) EMERGENCY SERVICES.—A summary of
20 the rules and procedures for accessing emergency
21 services, including the right of a participant, bene-
22 ficiary, or enrollee to obtain emergency services
23 under the prudent layperson standard under section
24 113, if such section applies, and any educational in-

1 formation that the plan or issuer may provide re-
2 garding the appropriate use of emergency services.

3 (12) CLAIMS AND APPEALS.—A description of
4 the plan or issuer's rules and procedures pertaining
5 to claims and appeals, a description of the rights
6 (including deadlines for exercising rights) of partici-
7 pants, beneficiaries, and enrollees under subtitle A
8 in obtaining covered benefits, filing a claim for bene-
9 fits, and appealing coverage decisions internally and
10 externally (including telephone numbers and mailing
11 addresses of the appropriate authority), and a de-
12 scription of any additional legal rights and remedies
13 available under section 502 of the Employee Retirement
14 Income Security Act of 1974 and applicable
15 State law.

16 (13) ADVANCE DIRECTIVES AND ORGAN DONA-
17 TION.—A description of procedures for advance di-
18 rectives and organ donation decisions if the plan or
19 issuer maintains such procedures.

20 (14) INFORMATION ON PLANS AND ISSUERS.—
21 The name, mailing address, and telephone number
22 or numbers of the plan administrator and the issuer
23 to be used by participants, beneficiaries, and enroll-
24 ees seeking information about plan or coverage bene-
25 fits and services, payment of a claim, or authoriza-

1 tion for services and treatment. Notice of whether
2 the benefits under the plan or coverage are provided
3 under a contract or policy of insurance issued by an
4 issuer, or whether benefits are provided directly by
5 the plan sponsor who bears the insurance risk.

6 (15) TRANSLATION SERVICES.—A summary de-
7 scription of any translation or interpretation services
8 (including the availability of printed information in
9 languages other than English, audio tapes, or infor-
10 mation in Braille) that are available for non-English
11 speakers and participants, beneficiaries, and enroll-
12 ees with communication disabilities and a description
13 of how to access these items or services.

14 (16) ACCREDITATION INFORMATION.—Any in-
15 formation that is made public by accrediting organi-
16 zations in the process of accreditation if the plan or
17 issuer is accredited, or any additional quality indica-
18 tors (such as the results of enrollee satisfaction sur-
19 veys) that the plan or issuer makes public or makes
20 available to participants, beneficiaries, and enrollees.

21 (17) NOTICE OF REQUIREMENTS.—A descrip-
22 tion of any rights of participants, beneficiaries, and
23 enrollees that are established by the Bipartisan Pa-
24 tient Protection Act of 2001 (excluding those de-
25 scribed in paragraphs (1) through (16)) if such sec-

1 tions apply. The description required under this
2 paragraph may be combined with the notices of the
3 type described in sections 711(d), 713(b), or
4 606(a)(1) of the Employee Retirement Income Secu-
5 rity Act of 1974 and with any other notice provision
6 that the appropriate Secretary determines may be
7 combined, so long as such combination does not re-
8 sult in any reduction in the information that would
9 otherwise be provided to the recipient.

10 (18) AVAILABILITY OF ADDITIONAL INFORMA-
11 TION.—A statement that the information described
12 in subsection (c), and instructions on obtaining such
13 information (including telephone numbers and, if
14 available, Internet websites), shall be made available
15 upon request.

16 (c) ADDITIONAL INFORMATION.—The informational
17 materials to be provided upon the request of a participant,
18 beneficiary, or enrollee shall include for each option avail-
19 able under a group health plan or health insurance cov-
20 erage the following:

21 (1) STATUS OF PROVIDERS.—The State licen-
22 sure status of the plan or issuer's participating
23 health care professionals and participating health
24 care facilities, and, if available, the education, train-

1 ing, specialty qualifications or certifications of such
2 professionals.

3 (2) COMPENSATION METHODS.—A summary
4 description by category of the applicable methods
5 (such as capitation, fee-for-service, salary, bundled
6 payments, per diem, or a combination thereof) used
7 for compensating prospective or treating health care
8 professionals (including primary care providers and
9 specialists) and facilities in connection with the pro-
10 vision of health care under the plan or coverage.

11 (3) PRESCRIPTION DRUGS.—Information about
12 whether a specific prescription medication is in-
13 cluded in the formulary of the plan or issuer, if the
14 plan or issuer uses a defined formulary.

15 (4) EXTERNAL APPEALS INFORMATION.—Ag-
16 gregate information on the number and outcomes of
17 external medical reviews, relative to the sample size
18 (such as the number of covered lives) under the plan
19 or under the coverage of the issuer.

20 (d) MANNER OF DISCLOSURE.—The information de-
21 scribed in this section shall be disclosed in an accessible
22 medium and format that is calculated to be understood
23 by an average participant or enrollee.

24 (e) RULES OF CONSTRUCTION.—Nothing in this sec-
25 tion shall be construed to prohibit a group health plan,

1 or a health insurance issuer in connection with health in-
2 surance coverage, from—

3 (1) distributing any other additional informa-
4 tion determined by the plan or issuer to be impor-
5 tant or necessary in assisting participants, bene-
6 ficiaries, and enrollees in the selection of a health
7 plan or health insurance coverage; and

8 (2) complying with the provisions of this section
9 by providing information in brochures, through the
10 Internet or other electronic media, or through other
11 similar means, so long as—

12 (A) the disclosure of such information in
13 such form is in accordance with requirements
14 as the appropriate Secretary may impose, and

15 (B) in connection with any such disclosure
16 of information through the Internet or other
17 electronic media—

18 (i) the recipient has affirmatively con-
19 sented to the disclosure of such informa-
20 tion in such form,

21 (ii) the recipient is capable of access-
22 ing the information so disclosed on the re-
23 cipient's individual workstation or at the
24 recipient's home,

(iii) the recipient retains an ongoing right to receive paper disclosure of such information and receives, in advance of any attempt at disclosure of such information to him or her through the Internet or other electronic media, notice in printed form of such ongoing right and of the proper software required to view information so disclosed, and

(iv) the plan administrator appropriately ensures that the intended recipient is receiving the information so disclosed and provides the information in printed form if the information is not received.

Subtitle D—Protecting the Doctor-Patient Relationship

SEC. 131. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.

(a) GENERAL RULE.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan or health insurance issuer in relation to health insurance coverage (including any partnership, association, or other organization that enters into or administers such a contract or agreement) and a health care provider (or group of health care pro-

1 viders) shall not prohibit or otherwise restrict a health
 2 care professional from advising such a participant, bene-
 3 ficiary, or enrollee who is a patient of the professional
 4 about the health status of the individual or medical care
 5 or treatment for the individual's condition or disease, re-
 6 gardless of whether benefits for such care or treatment
 7 are provided under the plan or coverage, if the professional
 8 is acting within the lawful scope of practice.

9 (b) NULLIFICATION.—Any contract provision or
 10 agreement that restricts or prohibits medical communica-
 11 tions in violation of subsection (a) shall be null and void.

12 **SEC. 132. PROHIBITION OF DISCRIMINATION AGAINST PRO-**
 13 **VIDERS BASED ON LICENSURE.**

14 (a) IN GENERAL.—A group health plan, and a health
 15 insurance issuer with respect to health insurance coverage,
 16 shall not discriminate with respect to participation or in-
 17 demnification as to any provider who is acting within the
 18 scope of the provider's license or certification under appli-
 19 cable State law, solely on the basis of such license or cer-
 20 tification.

21 (b) CONSTRUCTION.—Subsection (a) shall not be
 22 construed—

23 (1) as requiring the coverage under a group
 24 health plan or health insurance coverage of a par-
 25 ticular benefit or service or to prohibit a plan or

1 issuer from including providers only to the extent
 2 necessary to meet the needs of the plan's or issuer's
 3 participants, beneficiaries, or enrollees or from es-
 4 tablishing any measure designed to maintain quality
 5 and control costs consistent with the responsibilities
 6 of the plan or issuer;

7 (2) to override any State licensure or scope-of-
 8 practice law; or

9 (3) as requiring a plan or issuer that offers net-
 10 work coverage to include for participation every will-
 11 ing provider who meets the terms and conditions of
 12 the plan or issuer.

13 **SEC. 133. PROHIBITION AGAINST IMPROPER INCENTIVE**
 14 **ARRANGEMENTS.**

15 (a) IN GENERAL.—A group health plan and a health
 16 insurance issuer offering health insurance coverage may
 17 not operate any physician incentive plan (as defined in
 18 subparagraph (B) of section 1876(i)(8) of the Social Secu-
 19 rity Act) unless the requirements described in clauses (i),
 20 (ii)(I), and (iii) of subparagraph (A) of such section are
 21 met with respect to such a plan.

22 (b) APPLICATION.—For purposes of carrying out
 23 paragraph (1), any reference in section 1876(i)(8) of the
 24 Social Security Act to the Secretary, an eligible organiza-
 25 tion, or an individual enrolled with the organization shall

1 be treated as a reference to the applicable authority, a
2 group health plan or health insurance issuer, respectively,
3 and a participant, beneficiary, or enrollee with the plan
4 or organization, respectively.

5 (c) CONSTRUCTION.—Nothing in this section shall be
6 construed as prohibiting all capitation and similar ar-
7 rangements or all provider discount arrangements.

8 **SEC. 134. PAYMENT OF CLAIMS.**

9 A group health plan, and a health insurance issuer
10 offering group health insurance coverage, shall provide for
11 prompt payment of claims submitted for health care serv-
12 ices or supplies furnished to a participant, beneficiary, or
13 enrollee with respect to benefits covered by the plan or
14 issuer, in a manner consistent with the provisions of sec-
15 tion 1842(c)(2) of the Social Security Act (42 U.S.C.
16 1395u(c)(2)).

17 **SEC. 135. PROTECTION FOR PATIENT ADVOCACY.**

18 (a) PROTECTION FOR USE OF UTILIZATION REVIEW
19 AND GRIEVANCE PROCESS.—A group health plan, and a
20 health insurance issuer with respect to the provision of
21 health insurance coverage, may not retaliate against a par-
22 ticipant, beneficiary, enrollee, or health care provider
23 based on the participant's, beneficiary's, enrollee's or pro-
24 vider's use of, or participation in, a utilization review proc-
25 ess or a grievance process of the plan or issuer (including

1 an internal or external review or appeal process) under
2 this title.

3 (b) PROTECTION FOR QUALITY ADVOCACY BY
4 HEALTH CARE PROFESSIONALS.—

5 (1) IN GENERAL.—A group health plan or
6 health insurance issuer may not retaliate or dis-
7 criminate against a protected health care profes-
8 sional because the professional in good faith—

9 (A) discloses information relating to the
10 care, services, or conditions affecting one or
11 more participants, beneficiaries, or enrollees of
12 the plan or issuer to an appropriate public reg-
13 ulatory agency, an appropriate private accredi-
14 tation body, or appropriate management per-
15 sonnel of the plan or issuer; or

16 (B) initiates, cooperates, or otherwise par-
17 ticipates in an investigation or proceeding by
18 such an agency with respect to such care, serv-
19 ices, or conditions.

20 If an institutional health care provider is a partici-
21 pating provider with such a plan or issuer or other-
22 wise receives payments for benefits provided by such
23 a plan or issuer, the provisions of the previous sen-
24 tence shall apply to the provider in relation to care,
25 services, or conditions affecting one or more patients

1 within an institutional health care provider in the
2 same manner as they apply to the plan or issuer in
3 relation to care, services, or conditions provided to
4 one or more participants, beneficiaries, or enrollees;
5 and for purposes of applying this sentence, any ref-
6 erence to a plan or issuer is deemed a reference to
7 the institutional health care provider.

8 (2) GOOD FAITH ACTION.—For purposes of
9 paragraph (1), a protected health care professional
10 is considered to be acting in good faith with respect
11 to disclosure of information or participation if, with
12 respect to the information disclosed as part of the
13 action—

14 (A) the disclosure is made on the basis of
15 personal knowledge and is consistent with that
16 degree of learning and skill ordinarily possessed
17 by health care professionals with the same li-
18 censure or certification and the same experi-
19 ence;

20 (B) the professional reasonably believes the
21 information to be true;

22 (C) the information evidences either a vio-
23 lation of a law, rule, or regulation, of an appli-
24 cable accreditation standard, or of a generally
25 recognized professional or clinical standard or

1 that a patient is in imminent hazard of loss of
2 life or serious injury; and

3 (D) subject to subparagraphs (B) and (C)
4 of paragraph (3), the professional has followed
5 reasonable internal procedures of the plan,
6 issuer, or institutional health care provider es-
7 tablished for the purpose of addressing quality
8 concerns before making the disclosure.

9 (3) EXCEPTION AND SPECIAL RULE.—

10 (A) GENERAL EXCEPTION.—Paragraph (1)
11 does not protect disclosures that would violate
12 Federal or State law or diminish or impair the
13 rights of any person to the continued protection
14 of confidentiality of communications provided
15 by such law.

16 (B) NOTICE OF INTERNAL PROCEDURES.—
17 Subparagraph (D) of paragraph (2) shall not
18 apply unless the internal procedures involved
19 are reasonably expected to be known to the
20 health care professional involved. For purposes
21 of this subparagraph, a health care professional
22 is reasonably expected to know of internal pro-
23 cedures if those procedures have been made
24 available to the professional through distribu-
25 tion or posting.

1 (C) INTERNAL PROCEDURE EXCEPTION.—

2 Subparagraph (D) of paragraph (2) also shall
3 not apply if—

4 (i) the disclosure relates to an immi-
5 nent hazard of loss of life or serious injury
6 to a patient;

7 (ii) the disclosure is made to an ap-
8 propriate private accreditation body pursu-
9 ant to disclosure procedures established by
10 the body; or

11 (iii) the disclosure is in response to an
12 inquiry made in an investigation or pro-
13 ceeding of an appropriate public regulatory
14 agency and the information disclosed is
15 limited to the scope of the investigation or
16 proceeding.

17 (4) ADDITIONAL CONSIDERATIONS.—It shall
18 not be a violation of paragraph (1) to take an ad-
19 verse action against a protected health care profes-
20 sional if the plan, issuer, or provider taking the ad-
21 verse action involved demonstrates that it would
22 have taken the same adverse action even in the ab-
23 sence of the activities protected under such para-
24 graph.

1 (5) NOTICE.—A group health plan, health in-
2 surance issuer, and institutional health care provider
3 shall post a notice, to be provided or approved by
4 the Secretary of Labor, setting forth excerpts from,
5 or summaries of, the pertinent provisions of this
6 subsection and information pertaining to enforce-
7 ment of such provisions.

8 (6) CONSTRUCTIONS.—

9 (A) DETERMINATIONS OF COVERAGE.—

10 Nothing in this subsection shall be construed to
11 prohibit a plan or issuer from making a deter-
12 mination not to pay for a particular medical
13 treatment or service or the services of a type of
14 health care professional.

15 (B) ENFORCEMENT OF PEER REVIEW PRO-

16 TOCOLS AND INTERNAL PROCEDURES.—Noth-
17 ing in this subsection shall be construed to pro-
18 hibit a plan, issuer, or provider from estab-
19 lishing and enforcing reasonable peer review or
20 utilization review protocols or determining
21 whether a protected health care professional has
22 complied with those protocols or from estab-
23 lishing and enforcing internal procedures for
24 the purpose of addressing quality concerns.

1 (C) RELATION TO OTHER RIGHTS.—Noth-
 2 ing in this subsection shall be construed to
 3 abridge rights of participants, beneficiaries, en-
 4 rollees, and protected health care professionals
 5 under other applicable Federal or State laws.

6 (7) PROTECTED HEALTH CARE PROFESSIONAL
 7 DEFINED.—For purposes of this subsection, the
 8 term “protected health care professional” means an
 9 individual who is a licensed or certified health care
 10 professional and who—

11 (A) with respect to a group health plan or
 12 health insurance issuer, is an employee of the
 13 plan or issuer or has a contract with the plan
 14 or issuer for provision of services for which ben-
 15 efits are available under the plan or issuer; or

16 (B) with respect to an institutional health
 17 care provider, is an employee of the provider or
 18 has a contract or other arrangement with the
 19 provider respecting the provision of health care
 20 services.

21 **Subtitle E—Definitions**

22 **SEC. 151. DEFINITIONS.**

23 (a) INCORPORATION OF GENERAL DEFINITIONS.—
 24 Except as otherwise provided, the provisions of section
 25 2791 of the Public Health Service Act shall apply for pur-

1 poses of this title in the same manner as they apply for
2 purposes of title XXVII of such Act.

3 (b) SECRETARY.—Except as otherwise provided, the
4 term “Secretary” means the Secretary of Health and
5 Human Services, in consultation with the Secretary of
6 Labor and the term “appropriate Secretary” means the
7 Secretary of Health and Human Services in relation to
8 carrying out this title under sections 2706 and 2751 of
9 the Public Health Service Act and the Secretary of Labor
10 in relation to carrying out this title under section 713 of
11 the Employee Retirement Income Security Act of 1974.

12 (c) ADDITIONAL DEFINITIONS.—For purposes of this
13 title:

14 (1) APPLICABLE AUTHORITY.—The term “ap-
15 plicable authority” means—

16 (A) in the case of a group health plan, the
17 Secretary of Health and Human Services and
18 the Secretary of Labor; and

19 (B) in the case of a health insurance issuer
20 with respect to a specific provision of this title,
21 the applicable State authority (as defined in
22 section 2791(d) of the Public Health Service
23 Act), or the Secretary of Health and Human
24 Services, if such Secretary is enforcing such

1 provision under section 2722(a)(2) or
2 2761(a)(2) of the Public Health Service Act.

3 (3) ENROLLEE.—The term “enrollee” means,
4 with respect to health insurance coverage offered by
5 a health insurance issuer, an individual enrolled with
6 the issuer to receive such coverage.

7 (4) GROUP HEALTH PLAN.—The term “group
8 health plan” has the meaning given such term in
9 section 733(a) of the Employee Retirement Income
10 Security Act of 1974, except that such term includes
11 a employee welfare benefit plan treated as a group
12 health plan under section 732(d) of such Act or de-
13 fined as such a plan under section 607(1) of such
14 Act.

15 (5) HEALTH CARE PROFESSIONAL.—The term
16 “health care professional” means an individual who
17 is licensed, accredited, or certified under State law
18 to provide specified health care services and who is
19 operating within the scope of such licensure, accredi-
20 tation, or certification.

21 (6) HEALTH CARE PROVIDER.—The term
22 “health care provider” includes a physician or other
23 health care professional, as well as an institutional
24 or other facility or agency that provides health care
25 services and that is licensed, accredited, or certified

1 to provide health care items and services under ap-
2 plicable State law.

3 (7) NETWORK.—The term “network” means,
4 with respect to a group health plan or health insur-
5 ance issuer offering health insurance coverage, the
6 participating health care professionals and providers
7 through whom the plan or issuer provides health
8 care items and services to participants, beneficiaries,
9 or enrollees.

10 (8) NONPARTICIPATING.—The term “non-
11 participating” means, with respect to a health care
12 provider that provides health care items and services
13 to a participant, beneficiary, or enrollee under group
14 health plan or health insurance coverage, a health
15 care provider that is not a participating health care
16 provider with respect to such items and services.

17 (9) PARTICIPATING.—The term “participating”
18 means, with respect to a health care provider that
19 provides health care items and services to a partici-
20 pant, beneficiary, or enrollee under group health
21 plan or health insurance coverage offered by a
22 health insurance issuer, a health care provider that
23 furnishes such items and services under a contract
24 or other arrangement with the plan or issuer.

1 (10) PRIOR AUTHORIZATION.—The term “prior
2 authorization” means the process of obtaining prior
3 approval from a health insurance issuer or group
4 health plan for the provision or coverage of medical
5 services.

6 (11) TERMS AND CONDITIONS.—The term
7 “terms and conditions” includes, with respect to a
8 group health plan or health insurance coverage, re-
9 quirements imposed under this title with respect to
10 the plan or coverage.

11 **SEC. 152. PREEMPTION; STATE FLEXIBILITY; CONSTRUC-**
12 **TION.**

13 (a) CONTINUED APPLICABILITY OF STATE LAW
14 WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

15 (1) IN GENERAL.—Subject to paragraph (2),
16 this title shall not be construed to supersede any
17 provision of State law which establishes, implements,
18 or continues in effect any standard or requirement
19 solely relating to health insurance issuers (in connec-
20 tion with group health insurance coverage or other-
21 wise) except to the extent that such standard or re-
22 quirement prevents the application of a requirement
23 of this title.

24 (2) CONTINUED PREEMPTION WITH RESPECT
25 TO GROUP HEALTH PLANS.—Nothing in this title

1 shall be construed to affect or modify the provisions
2 of section 514 of the Employee Retirement Income
3 Security Act of 1974 with respect to group health
4 plans.

5 (3) CONSTRUCTION.—In applying this section,
6 a State law that provides for equal access to, and
7 availability of, all categories of licensed health care
8 providers and services shall not be treated as pre-
9 venting the application of any requirement of this
10 title.

11 (b) APPLICATION OF SUBSTANTIALLY EQUIVALENT
12 STATE LAWS.—

13 (1) IN GENERAL.—In the case of a State law
14 that imposes, with respect to health insurance cov-
15 erage offered by a health insurance issuer and with
16 respect to a group health plan that is a non-Federal
17 governmental plan, a requirement that is substan-
18 tially equivalent (within the meaning of subsection
19 (c)) to a patient protection requirement (as defined
20 in paragraph (3)) and does not prevent the applica-
21 tion of other requirements under this Act (except in
22 the case of other substantially equivalent require-
23 ments), in applying the requirements of this title
24 under section 2707 and 2753 (as applicable) of the

1 Public Health Service Act (as added by title II),
2 subject to subsection (a)(2)—

3 (A) the State law shall not be treated as
4 being superseded under subsection (a); and

5 (B) the State law shall apply instead of the
6 patient protection requirement otherwise appli-
7 cable with respect to health insurance coverage
8 and non-Federal governmental plans.

9 (2) LIMITATION.—In the case of a group health
10 plan covered under title I of the Employee Retirement
11 Income Security Act of 1974, paragraph (1)
12 shall be construed to apply only with respect to the
13 health insurance coverage (if any) offered in connec-
14 tion with the plan.

15 (3) PATIENT PROTECTION REQUIREMENT DE-
16 FINED.—For purposes of this section, the term “pa-
17 tient protection requirement” means a requirement
18 under this title, and includes (as a single require-
19 ment) a group or related set of requirements under
20 a section or similar unit under this title.

21 (c) DETERMINATIONS OF SUBSTANTIAL EQUIVA-
22 LENCE.—

23 (1) CERTIFICATION BY STATES.—A State may
24 submit to the Secretary a certification that a State
25 law provides for patient protections that are at least

1 substantially equivalent to one or more patient pro-
2 tection requirements. Such certification shall be ac-
3 companied by such information as may be required
4 to permit the Secretary to make the determination
5 described in paragraph (2)(A).

6 (2) REVIEW.—

7 (A) IN GENERAL.—The Secretary shall
8 promptly review a certification submitted under
9 paragraph (1) with respect to a State law to de-
10 termine if the State law provides for at least
11 substantially equivalent and effective patient
12 protections to the patient protection require-
13 ment (or requirements) to which the law re-
14 lates.

15 (B) APPROVAL DEADLINES.—

16 (i) INITIAL REVIEW.—Such a certifi-
17 cation is considered approved unless the
18 Secretary notifies the State in writing,
19 within 90 days after the date of receipt of
20 the certification, that the certification is
21 disapproved (and the reasons for dis-
22 approval) or that specified additional infor-
23 mation is needed to make the determina-
24 tion described in subparagraph (A).

1 (ii) ADDITIONAL INFORMATION.—

2 With respect to a State that has been noti-
3 fied by the Secretary under clause (i) that
4 specified additional information is needed
5 to make the determination described in
6 subparagraph (A), the Secretary shall
7 make the determination within 60 days
8 after the date on which such specified ad-
9 ditional information is received by the Sec-
10 retary.

11 (3) APPROVAL.—

12 (A) IN GENERAL.—The Secretary shall ap-
13 prove a certification under paragraph (1)
14 unless—

15 (i) the State fails to provide sufficient
16 information to enable the Secretary to
17 make a determination under paragraph
18 (2)(A); or

19 (ii) the Secretary determines that the
20 State law involved does not provide for pa-
21 tient protections that are at least substan-
22 tially equivalent to and as effective as the
23 patient protection requirement (or require-
24 ments) to which the law relates.

1 (B) STATE CHALLENGE.—A State that has
2 a certification disapproved by the Secretary
3 under subparagraph (A) may challenge such
4 disapproval in the appropriate United States
5 district court.

6 (4) CONSTRUCTION.—Nothing in this sub-
7 section shall be construed as preventing the certifi-
8 cation (and approval of certification) of a State law
9 under this subsection solely because it provides for
10 greater protections for patients than those protec-
11 tions otherwise required to establish substantial
12 equivalence.

13 (d) DEFINITIONS.—For purposes of this section:

14 (1) STATE LAW.—The term “State law” in-
15 cludes all laws, decisions, rules, regulations, or other
16 State action having the effect of law, of any State.
17 A law of the United States applicable only to the
18 District of Columbia shall be treated as a State law
19 rather than a law of the United States.

20 (2) STATE.—The term “State” includes a
21 State, the District of Columbia, Puerto Rico, the
22 Virgin Islands, Guam, American Samoa, the North-
23 ern Mariana Islands, any political subdivisions of
24 such, or any agency or instrumentality of such.

1 **SEC. 153. EXCLUSIONS.**

2 (a) NO BENEFIT REQUIREMENTS.—Nothing in this
3 title shall be construed to require a group health plan or
4 a health insurance issuer offering health insurance cov-
5 erage to include specific items and services under the
6 terms of such a plan or coverage, other than those pro-
7 vided under the terms and conditions of such plan or cov-
8 erage.

9 (b) EXCLUSION FROM ACCESS TO CARE MANAGED
10 CARE PROVISIONS FOR FEE-FOR-SERVICE COVERAGE.—

11 (1) IN GENERAL.—The provisions of sections
12 111 through 117 shall not apply to a group health
13 plan or health insurance coverage if the only cov-
14 erage offered under the plan or coverage is fee-for-
15 service coverage (as defined in paragraph (2)).

16 (2) FEE-FOR-SERVICE COVERAGE DEFINED.—
17 For purposes of this subsection, the term “fee-for-
18 service coverage” means coverage under a group
19 health plan or health insurance coverage that—

20 (A) reimburses hospitals, health profes-
21 sionals, and other providers on a fee-for-service
22 basis without placing the provider at financial
23 risk;

24 (B) does not vary reimbursement for such
25 a provider based on an agreement to contract

1 terms and conditions or the utilization of health
2 care items or services relating to such provider;

3 (C) allows access to any provider that is
4 lawfully authorized to provide the covered serv-
5 ices and that agrees to accept the terms and
6 conditions of payment established under the
7 plan or by the issuer; and

8 (D) for which the plan or issuer does not
9 require prior authorization before providing for
10 any health care services.

11 **SEC. 154. COVERAGE OF LIMITED SCOPE PLANS.**

12 Only for purposes of applying the requirements of
13 this title under sections 2707 and 2753 of the Public
14 Health Service Act and section 714 of the Employee Re-
15 tirement Income Security Act of 1974, section
16 2791(c)(2)(A), and section 733(c)(2)(A) of the Employee
17 Retirement Income Security Act of 1974 shall be deemed
18 not to apply.

19 **SEC. 155. REGULATIONS.**

20 The Secretaries of Health and Human Services and
21 Labor shall issue such regulations as may be necessary
22 or appropriate to carry out this title. Such regulations
23 shall be issued consistent with section 104 of Health In-
24 surance Portability and Accountability Act of 1996. Such
25 Secretaries may promulgate any interim final rules as the

1 Secretaries determine are appropriate to carry out this
2 title.

3 **SEC. 156. INCORPORATION INTO PLAN OR COVERAGE DOC-**
4 **UMENTS.**

5 The requirements of this title with respect to a group
6 health plan or health insurance coverage are deemed to
7 be incorporated into, and made a part of, such plan or
8 the policy, certificate, or contract providing such coverage
9 and are enforceable under law as if directly included in
10 the documentation of such plan or such policy, certificate,
11 or contract.

12 **TITLE II—APPLICATION OF**
13 **QUALITY CARE STANDARDS**
14 **TO GROUP HEALTH PLANS**
15 **AND HEALTH INSURANCE**
16 **COVERAGE UNDER THE PUB-**
17 **LIC HEALTH SERVICE ACT**

18 **SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND**
19 **GROUP HEALTH INSURANCE COVERAGE.**

20 (a) IN GENERAL.—Subpart 2 of part A of title
21 XXVII of the Public Health Service Act is amended by
22 adding at the end the following new section:

23 **“SEC. 2707. PATIENT PROTECTION STANDARDS.**

24 “Each group health plan shall comply with patient
25 protection requirements under title I of the Bipartisan Pa-

1 tient Protection Act of 2001, and each health insurance
 2 issuer shall comply with patient protection requirements
 3 under such title with respect to group health insurance
 4 coverage it offers, and such requirements shall be deemed
 5 to be incorporated into this subsection.”.

6 (b) CONFORMING AMENDMENT.—Section
 7 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A))
 8 is amended by inserting “(other than section 2707)” after
 9 “requirements of such subparts”.

10 **SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSUR-**
 11 **ANCE COVERAGE.**

12 Part B of title XXVII of the Public Health Service
 13 Act is amended by inserting after section 2752 the fol-
 14 lowing new section:

15 **“SEC. 2753. PATIENT PROTECTION STANDARDS.**

16 “Each health insurance issuer shall comply with pa-
 17 tient protection requirements under title I of the Bipar-
 18 tisan Patient Protection Act of 2001 with respect to indi-
 19 vidual health insurance coverage it offers, and such re-
 20 quirements shall be deemed to be incorporated into this
 21 subsection.”.

1 **TITLE III—AMENDMENTS TO**
 2 **THE EMPLOYEE RETIREMENT**
 3 **INCOME SECURITY ACT OF**
 4 **1974**

5 **SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-**
 6 **ARDS TO GROUP HEALTH PLANS AND GROUP**
 7 **HEALTH INSURANCE COVERAGE UNDER THE**
 8 **EMPLOYEE RETIREMENT INCOME SECURITY**
 9 **ACT OF 1974.**

10 Subpart B of part 7 of subtitle B of title I of the
 11 Employee Retirement Income Security Act of 1974 is
 12 amended by adding at the end the following new section:

13 **“SEC. 714. PATIENT PROTECTION STANDARDS.**

14 “(a) IN GENERAL.—Subject to subsection (b), a
 15 group health plan (and a health insurance issuer offering
 16 group health insurance coverage in connection with such
 17 a plan) shall comply with the requirements of title I of
 18 the Bipartisan Patient Protection Act of 2001 (as in effect
 19 as of the date of the enactment of such Act), and such
 20 requirements shall be deemed to be incorporated into this
 21 subsection.

22 “(b) PLAN SATISFACTION OF CERTAIN REQUIRE-
 23 MENTS.—

24 “(1) SATISFACTION OF CERTAIN REQUIRE-
 25 MENTS THROUGH INSURANCE.—For purposes of

1 subsection (a), insofar as a group health plan pro-
2 vides benefits in the form of health insurance cov-
3 erage through a health insurance issuer, the plan
4 shall be treated as meeting the following require-
5 ments of title I of the Bipartisan Patient Protection
6 Act of 2001 with respect to such benefits and not
7 be considered as failing to meet such requirements
8 because of a failure of the issuer to meet such re-
9 quirements so long as the plan sponsor or its rep-
10 resentatives did not cause such failure by the issuer:

11 “(A) Section 111 (relating to consumer
12 choice option).

13 “(B) Section 112 (relating to choice of
14 health care professional).

15 “(C) Section 113 (relating to access to
16 emergency care).

17 “(D) Section 114 (relating to timely access
18 to specialists).

19 “(E) Section 115 (relating to patient ac-
20 cess to obstetrical and gynecological care).

21 “(F) Section 116 (relating to access to pe-
22 diatric care).

23 “(G) Section 117 (relating to continuity of
24 care), but only insofar as a replacement issuer
25 assumes the obligation for continuity of care.

1 “(H) Section 118 (relating to access to
2 needed prescription drugs).

3 “(I) Section 119 (relating to coverage for
4 individuals participating in approved clinical
5 trials).

6 “(J) Section 120 (relating to required cov-
7 erage for minimum hospital stay for
8 mastectomies and lymph node dissections for
9 the treatment of breast cancer and coverage for
10 secondary consultations).

11 “(K) Section 134 (relating to payment of
12 claims).

13 “(2) INFORMATION.—With respect to informa-
14 tion required to be provided or made available under
15 section 121 of the Bipartisan Patient Protection Act
16 of 2001, in the case of a group health plan that pro-
17 vides benefits in the form of health insurance cov-
18 erage through a health insurance issuer, the Sec-
19 retary shall determine the circumstances under
20 which the plan is not required to provide or make
21 available the information (and is not liable for the
22 issuer’s failure to provide or make available the in-
23 formation), if the issuer is obligated to provide and
24 make available (or provides and makes available)
25 such information.

1 “(3) INTERNAL APPEALS.—With respect to the
2 internal appeals process required to be established
3 under section 103 of such Act, in the case of a
4 group health plan that provides benefits in the form
5 of health insurance coverage through a health insur-
6 ance issuer, the Secretary shall determine the cir-
7 cumstances under which the plan is not required to
8 provide for such process and system (and is not lia-
9 ble for the issuer’s failure to provide for such proc-
10 ess and system), if the issuer is obligated to provide
11 for (and provides for) such process and system.

12 “(4) EXTERNAL APPEALS.—Pursuant to rules
13 of the Secretary, insofar as a group health plan en-
14 ters into a contract with a qualified external appeal
15 entity for the conduct of external appeal activities in
16 accordance with section 104 of such Act, the plan
17 shall be treated as meeting the requirement of such
18 section and is not liable for the entity’s failure to
19 meet any requirements under such section.

20 “(5) APPLICATION TO PROHIBITIONS.—Pursu-
21 ant to rules of the Secretary, if a health insurance
22 issuer offers health insurance coverage in connection
23 with a group health plan and takes an action in vio-
24 lation of any of the following sections of the Bipar-
25 tisan Patient Protection Act of 2001, the group

1 health plan shall not be liable for such violation un-
2 less the plan caused such violation:

3 “(A) Section 131 (relating to prohibition of
4 interference with certain medical communica-
5 tions).

6 “(B) Section 132 (relating to prohibition
7 of discrimination against providers based on li-
8 censure).

9 “(C) Section 133 (relating to prohibition
10 against improper incentive arrangements).

11 “(D) Section 135 (relating to protection
12 for patient advocacy).

13 “(6) CONSTRUCTION.—Nothing in this sub-
14 section shall be construed to affect or modify the re-
15 sponsibilities of the fiduciaries of a group health
16 plan under part 4 of subtitle B.

17 “(7) TREATMENT OF SUBSTANTIALLY EQUIVA-
18 LENT STATE LAWS.—For purposes of applying this
19 subsection, any reference in this subsection to a re-
20 quirement in a section or other provision in the Bi-
21 partisan Patient Protection Act of 2001 with respect
22 to a health insurance issuer is deemed to include a
23 reference to a requirement under a State law that is
24 substantially equivalent (as determined under section

1 152(c) of such Act) to the requirement in such sec-
2 tion or other provisions.

3 “(8) APPLICATION TO CERTAIN PROHIBITIONS
4 AGAINST RETALIATION.—With respect to compliance
5 with the requirements of section 135(b)(1) of the Bi-
6 partisan Patient Protection Act of 2001, for pur-
7 poses of this subtitle the term ‘group health plan’ is
8 deemed to include a reference to an institutional
9 health care provider.

10 “(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

11 “(1) COMPLAINTS.—Any protected health care
12 professional who believes that the professional has
13 been retaliated or discriminated against in violation
14 of section 135(b)(1) of the Bipartisan Patient Pro-
15 tection Act of 2001 may file with the Secretary a
16 complaint within 180 days of the date of the alleged
17 retaliation or discrimination.

18 “(2) INVESTIGATION.—The Secretary shall in-
19 vestigate such complaints and shall determine if a
20 violation of such section has occurred and, if so,
21 shall issue an order to ensure that the protected
22 health care professional does not suffer any loss of
23 position, pay, or benefits in relation to the plan,
24 issuer, or provider involved, as a result of the viola-
25 tion found by the Secretary.

1 “(d) CONFORMING REGULATIONS.—The Secretary
2 shall issue regulations to coordinate the requirements on
3 group health plans and health insurance issuers under this
4 section with the requirements imposed under the other
5 provisions of this title. In order to reduce duplication and
6 clarify the rights of participants and beneficiaries with re-
7 spect to information that is required to be provided, such
8 regulations shall coordinate the information disclosure re-
9 quirements under section 121 of the Bipartisan Patient
10 Protection Act of 2001 with the reporting and disclosure
11 requirements imposed under part 1, so long as such co-
12 ordination does not result in any reduction in the informa-
13 tion that would otherwise be provided to participants and
14 beneficiaries.”.

15 (b) SATISFACTION OF ERISA CLAIMS PROCEDURE
16 REQUIREMENT.—Section 503 of such Act (29 U.S.C.
17 1133) is amended by inserting “(a)” after “SEC. 503.”
18 and by adding at the end the following new subsection:

19 “(b) In the case of a group health plan (as defined
20 in section 733) compliance with the requirements of sub-
21 title A of title I of the Bipartisan Patient Protection Act
22 of 2001, and compliance with regulations promulgated by
23 the Secretary, in the case of a claims denial shall be
24 deemed compliance with subsection (a) with respect to
25 such claims denial.”.

1 (c) CONFORMING AMENDMENTS.—(1) Section 732(a)
 2 of such Act (29 U.S.C. 1185(a)) is amended by striking
 3 “section 711” and inserting “sections 711 and 714”.

4 (2) The table of contents in section 1 of such Act
 5 is amended by inserting after the item relating to section
 6 713 the following new item:

“Sec. 714. Patient protection standards.”.

7 (3) Section 502(b)(3) of such Act (29 U.S.C.
 8 1132(b)(3)) is amended by inserting “(other than section
 9 135(b))” after “part 7”.

10 **SEC. 302. AVAILABILITY OF CIVIL REMEDIES.**

11 (a) AVAILABILITY OF FEDERAL CIVIL REMEDIES IN
 12 CASES NOT INVOLVING MEDICALLY REVIEWABLE DECISIONS.—
 13

14 (1) IN GENERAL.—Section 502 of the Employee
 15 Retirement Income Security Act of 1974 (29 U.S.C.
 16 1132) is amended by adding at the end the following
 17 new subsection:

18 “(n) CAUSE OF ACTION RELATING TO PROVISION OF
 19 HEALTH BENEFITS.—

20 “(1) IN GENERAL.—In any case in which—

21 “(A) a person who is a fiduciary of a
 22 group health plan, a health insurance issuer of-
 23 fering health insurance coverage in connection
 24 with the plan, or an agent of the plan, issuer,
 25 or plan sponsor—

1 “(i) upon consideration of a claim for
2 benefits of a participant or beneficiary
3 under section 102 of the Bipartisan Pa-
4 tient Protection Act of 2001 (relating to
5 procedures for initial claims for benefits
6 and prior authorization determinations) or
7 upon review of a denial of such a claim
8 under section 103 of such Act (relating to
9 internal appeal of a denial of a claim for
10 benefits), fails to exercise ordinary care in
11 making a decision—

12 “(I) regarding whether an item
13 or service is covered under the terms
14 and conditions of the plan or cov-
15 erage,

16 “(II) regarding whether an indi-
17 vidual is a participant or beneficiary
18 who is enrolled under the terms and
19 conditions of the plan or coverage (in-
20 cluding the applicability of any wait-
21 ing period under the plan or cov-
22 erage), or

23 “(III) as to the application of
24 cost-sharing requirements or the ap-
25 plication of a specific exclusion or ex-

1 press limitation on the amount, dura-
2 tion, or scope of coverage of items or
3 services under the terms and condi-
4 tions of the plan or coverage, or

5 “(ii) otherwise fails to exercise ordi-
6 nary care in the performance of a duty
7 under the terms and conditions of the plan
8 with respect to a participant or beneficiary,
9 and

10 “(B) such failure is a proximate cause of
11 personal injury to, or the death of, the partici-
12 pant or beneficiary,

13 such person shall be liable to the participant or ben-
14 eficiary (or the estate of such participant or bene-
15 ficiary) for economic and noneconomic damages (but
16 not exemplary or punitive damages) in connection
17 with such personal injury or death.

18 “(2) CAUSE OF ACTION MUST NOT INVOLVE
19 MEDICALLY REVIEWABLE DECISION.—

20 “(A) IN GENERAL.—A cause of action is
21 established under paragraph (1)(A) only if the
22 decision referred to in clause (i) or the failure
23 described in clause (ii) does not include a medi-
24 cally reviewable decision.

1 “(B) MEDICALLY REVIEWABLE DECI-
2 SION.—For purposes of subparagraph (A), the
3 term ‘medically reviewable decision’ means a de-
4 nial of a claim for benefits under the plan
5 which is described in section 104(d)(2) of the
6 Bipartisan Patient Protection Act of 2001 (re-
7 lating to medically reviewable decisions).

8 “(3) DEFINITIONS.—For purposes of this sub-
9 section.—

10 “(A) ORDINARY CARE.—The term ‘ordi-
11 nary care’ means—

12 “(i) with respect to a determination
13 on a claim for benefits, that degree of care,
14 skill, and diligence that a reasonable and
15 prudent individual would exercise in mak-
16 ing a fair determination on a claim for
17 benefits of like kind to the claim involved;
18 and

19 “(ii) with respect to the performance
20 of a duty, that degree of care, skill, and
21 diligence that a reasonable and prudent in-
22 dividual would exercise in performing the
23 duty or a duty of like character.

24 “(B) PERSONAL INJURY.—The term ‘per-
25 sonal injury’ means a physical injury and in-

1 includes an injury arising out of the treatment
2 (or failure to treat) a mental illness or disease.

3 “(C) CLAIM FOR BENEFITS; DENIAL.—The
4 terms ‘claim for benefits’ and ‘denial of a claim
5 for benefits’ have the meanings provided such
6 terms in section 102(e) of the Bipartisan Pa-
7 tient Protection Act of 2001.

8 “(D) TERMS AND CONDITIONS.—The term
9 ‘terms and conditions’ includes, with respect to
10 a group health plan or health insurance cov-
11 erage, requirements imposed under title I of the
12 Bipartisan Patient Protection Act of 2001 or
13 under part 6 or 7.

14 “(E) GROUP HEALTH PLAN AND OTHER
15 RELATED TERMS.—The provisions of sections
16 732(d) and 733 apply for purposes of this sub-
17 section in the same manner as they apply for
18 purposes of part 7, except that the term ‘group
19 health plan’ includes a group health plan (as
20 defined in section 607(1)).

21 “(4) EXCLUSION OF EMPLOYERS AND OTHER
22 PLAN SPONSORS.—

23 “(A) CAUSES OF ACTION AGAINST EM-
24 PLOYERS AND PLAN SPONSORS PRECLUDED.—
25 Subject to subparagraph (B), paragraph (1)(A)

1 does not authorize a cause of action against an
2 employer or other plan sponsor maintaining the
3 plan (or against an employee of such an em-
4 ployer or sponsor acting within the scope of em-
5 ployment).

6 “(B) CERTAIN CAUSES OF ACTION PER-
7 MITTED.—Notwithstanding subparagraph (A),
8 a cause of action may arise against an employer
9 or other plan sponsor (or against an employee
10 of such an employer or sponsor acting within
11 the scope of employment)—

12 “(i) under clause (i) of paragraph
13 (1)(A), to the extent there was direct par-
14 ticipation by the employer or other plan
15 sponsor (or employee) in the decision of
16 the plan under section 102 of the Bipar-
17 tisan Patient Protection Act of 2001 upon
18 consideration of a claim for benefits or
19 under section 103 of such Act upon review
20 of a denial of a claim for benefits, or

21 “(ii) under clause (ii) of paragraph
22 (1)(A), to the extent there was direct par-
23 ticipation by the employer or other plan
24 sponsor (or employee) in the failure de-
25 scribed in such clause.

1 “(C) DIRECT PARTICIPATION.—

2 “(i) DIRECT PARTICIPATION IN DECISIONS.—For purposes of subparagraph
3 (B), the term ‘direct participation’ means,
4 in connection with a decision described in
5 clause (i) of paragraph (1)(A) or a failure
6 described in clause (ii) of such paragraph,
7 the actual making of such decision or the
8 actual exercise of control in making such
9 decision or in the conduct constituting the
10 failure.
11

12 “(ii) RULES OF CONSTRUCTION.—For
13 purposes of clause (i), the employer or plan
14 sponsor (or employee) shall not be construed to be engaged in direct participation
15 because of any form of decisionmaking or
16 other conduct that is merely collateral or
17 precedent to the decision described in
18 clause (i) of paragraph (1)(A) on a particular claim for benefits of a participant
19 or beneficiary or that is merely collateral
20 or precedent to the conduct constituting a
21 failure described in clause (ii) of paragraph
22 (1)(A) with respect to a particular partici-
23
24

1 pant or beneficiary, including (but not lim-
2 ited to)—

3 “(I) any participation by the em-
4 ployer or other plan sponsor (or em-
5 ployee) in the selection of the group
6 health plan or health insurance cov-
7 erage involved or the third party ad-
8 ministrator or other agent;

9 “(II) any engagement by the em-
10 ployer or other plan sponsor (or em-
11 ployee) in any cost-benefit analysis
12 undertaken in connection with the se-
13 lection of, or continued maintenance
14 of, the plan or coverage involved;

15 “(III) any participation by the
16 employer or other plan sponsor (or
17 employee) in the process of creating,
18 continuing, modifying, or terminating
19 the plan or any benefit under the
20 plan, if such process was not substan-
21 tially focused solely on the particular
22 situation of the participant or bene-
23 ficiary referred to in paragraph
24 (1)(A); and

1 “(IV) any participation by the
2 employer or other plan sponsor (or
3 employee) in the design of any benefit
4 under the plan, including the amount
5 of copayment and limits connected
6 with such benefit.

7 “(iv) IRRELEVANCE OF CERTAIN COL-
8 LATERAL EFFORTS MADE BY EMPLOYER
9 OR PLAN SPONSOR.—For purposes of this
10 subparagraph, an employer or plan sponsor
11 shall not be treated as engaged in direct
12 participation in a decision with respect to
13 any claim for benefits or denial thereof in
14 the case of any particular participant or
15 beneficiary solely by reason of—

16 “(I) any efforts that may have
17 been made by the employer or plan
18 sponsor to advocate for authorization
19 of coverage for that or any other par-
20 ticipant or beneficiary (or any group
21 of participants or beneficiaries), or

22 “(II) any provision that may
23 have been made by the employer or
24 plan sponsor for benefits which are
25 not covered under the terms and con-

1 ditions of the plan for that or any
2 other participant or beneficiary (or
3 any group of participants or bene-
4 ficiaries).

5 “(5) REQUIREMENT OF EXHAUSTION.—

6 “(A) IN GENERAL.—Except as provided in
7 this paragraph, a cause of action may not be
8 brought under paragraph (1) in connection with
9 any denial of a claim for benefits of any indi-
10 vidual until all administrative processes under
11 sections 102 and 103 of the Bipartisan Patient
12 Protection Act of 2001 (if applicable) have been
13 exhausted.

14 “(B) LATE MANIFESTATION OF INJURY.—
15 The requirements under subparagraph (A) for a
16 cause of action in connection with any denial of
17 a claim for benefits shall be deemed satisfied,
18 notwithstanding any failure to timely commence
19 review under section 103 with respect to the de-
20 nial, if the personal injury is first known (or
21 first reasonably should have been known) to the
22 individual (or the death occurs) after the latest
23 date by which the applicable requirements of
24 subparagraph (A) can be met in connection
25 with such denial.

1 “(C) OCCURRENCE OF IMMEDIATE AND IR-
2 REPARABLE HARM OR DEATH PRIOR TO COM-
3 PLETION OF PROCESS.—

4 “(i) IN GENERAL.—The requirements
5 of subparagraph (A) shall not apply if the
6 action involves an allegation that imme-
7 diate and irreparable harm or death was,
8 or would be, caused by the denial of a
9 claim for benefits prior to the completion
10 of the administrative processes referred to
11 in subparagraph (A) with respect to such
12 denial.

13 “(ii) CONSTRUCTION.—Nothing in
14 clause (i) shall be construed to preclude—

15 “(I) continuation of such proc-
16 esses to their conclusion if so moved
17 by any party, and

18 “(II) consideration in such action
19 of the final decisions issued in such
20 processes.

21 “(iii) DEFINITION.—In clause (i), the
22 term ‘irreparable harm’, with respect to an
23 individual, means an injury or condition
24 that, regardless of whether the individual
25 receives the treatment that is the subject

1 of the denial, cannot be repaired in a man-
2 ner that would restore the individual to the
3 individual's pre-injured condition.

4 “(D) RECEIPT OF BENEFITS DURING AP-
5 PEALS PROCESS.—Receipt by the participant or
6 beneficiary of the benefits involved in the claim
7 for benefits during the pendency of any admin-
8 istrative processes referred to in subparagraph
9 (A) or of any action commenced under this
10 subsection—

11 “(i) shall not preclude continuation of
12 all such administrative processes to their
13 conclusion if so moved by any party, and

14 “(ii) shall not preclude any liability
15 under subsection (a)(1)(C) and this sub-
16 section in connection with such claim.

17 The court in any action commenced under this
18 subsection shall take into account any receipt of
19 benefits during such administrative processes or
20 such action in determining the amount of the
21 damages awarded.

22 “(6) STATUTORY DAMAGES.—

23 “(A) IN GENERAL.—The remedies set
24 forth in this subsection (n) shall be the exclu-

1 sive remedies for causes of action brought
2 under this subsection.

3 “(B) ASSESSMENT OF CIVIL PENALTIES.—

4 In addition to the remedies provided for in
5 paragraph (1) (relating to the failure to provide
6 contract benefits in accordance with the plan),
7 a civil assessment, in an amount not to exceed
8 \$5,000,000, payable to the claimant may be
9 awarded in any action under such paragraph if
10 the claimant establishes by clear and convincing
11 evidence that the alleged conduct carried out by
12 the defendant demonstrated bad faith and fla-
13 grant disregard for the rights of the participant
14 or beneficiary under the plan and was a proxi-
15 mate cause of the personal injury or death that
16 is the subject of the claim.

17 “(7) LIMITATION OF ACTION.—Paragraph (1)

18 shall not apply in connection with any action com-
19 menced after 3 years after the later of—

20 “(A) the date on which the plaintiff first
21 knew, or reasonably should have known, of the
22 personal injury or death resulting from the fail-
23 ure described in paragraph (1), or

24 “(B) the date as of which the requirements
25 of paragraph (5) are first met.

1 “(8) TOLLING PROVISION.—The statute of limi-
2 tations for any cause of action arising under State
3 law relating to a denial of a claim for benefits that
4 is the subject of an action brought in Federal court
5 under this subsection shall be tolled until such time
6 as the Federal court makes a final disposition, in-
7 cluding all appeals, of whether such claim should
8 properly be within the jurisdiction of the Federal
9 court. The tolling period shall be determined by the
10 applicable Federal or State law, whichever period is
11 greater.

12 “(9) PURCHASE OF INSURANCE TO COVER LI-
13 ABILITY.—Nothing in section 410 shall be construed
14 to preclude the purchase by a group health plan of
15 insurance to cover any liability or losses arising
16 under a cause of action under subsection (a)(1)(C)
17 and this subsection.

18 “(10) EXCLUSION OF DIRECTED RECORD-
19 KEEPERS.—

20 “(A) IN GENERAL.—Subject to subpara-
21 graph (C), paragraph (1) shall not apply with
22 respect to a directed recordkeeper in connection
23 with a group health plan.

24 “(B) DIRECTED RECORDKEEPER.—For
25 purposes of this paragraph, the term ‘directed

1 recordkeeper’ means, in connection with a
2 group health plan, a person engaged in directed
3 recordkeeping activities pursuant to the specific
4 instructions of the plan or the employer or
5 other plan sponsor, including the distribution of
6 enrollment information and distribution of dis-
7 closure materials under this Act or title I of the
8 Bipartisan Patient Protection Act of 2001 and
9 whose duties do not include making decisions
10 on claims for benefits.

11 “(C) LIMITATION.—Subparagraph (A)
12 does not apply in connection with any directed
13 recordkeeper to the extent that the directed rec-
14 ordkeeper fails to follow the specific instruction
15 of the plan or the employer or other plan spon-
16 sor.

17 “(11) NO EFFECT ON STATE LAW.—No provi-
18 sion of State law (as defined in section 514(c)(1))
19 shall be treated as superseded or otherwise altered,
20 amended, modified, invalidated, or impaired by rea-
21 son of the provisions of subsection (a)(1)(C) and this
22 subsection.”.

23 (2) CONFORMING AMENDMENT.—Section
24 502(a)(1) of such Act (29 U.S.C. 1132(a)(1)) is
25 amended—

1 (A) by striking “or” at the end of subpara-
 2 graph (A);

3 (B) in subparagraph (B), by striking
 4 “plan;” and inserting “plan, or”; and

5 (C) by adding at the end the following new
 6 subparagraph:

7 “(C) for the relief provided for in sub-
 8 section (n) of this section.”.

9 (b) RULES RELATING TO ERISA PREEMPTION.—
 10 Section 514 of the Employee Retirement Income Security
 11 Act of 1974 (29 U.S.C. 1144) is amended—

12 (1) by redesignating subsection (d) as sub-
 13 section (f); and

14 (2) by inserting after subsection (c) the fol-
 15 lowing new subsections:

16 “(d) PREEMPTION NOT TO APPLY TO CAUSES OF
 17 ACTION UNDER STATE LAW INVOLVING MEDICALLY RE-
 18 VIEWABLE DECISION.—

19 “(1) NON-PREEMPTION OF CERTAIN CAUSES OF
 20 ACTION.—

21 “(A) IN GENERAL.—Except as provided in
 22 this subsection, nothing in this title (including
 23 section 502) shall be construed to supersede or
 24 otherwise alter, amend, modify, invalidate, or
 25 impair any cause of action under State law of

1 a participant or beneficiary under a group
2 health plan (or the estate of such a participant
3 or beneficiary) to recover damages resulting
4 from personal injury or for wrongful death
5 against any person if such cause of action
6 arises by reason of a medically reviewable deci-
7 sion.

8 “(B) MEDICALLY REVIEWABLE DECI-
9 SION.—For purposes of subparagraph (A), the
10 term ‘medically reviewable decision’ means a de-
11 nial of a claim for benefits under the plan
12 which is described in section 104(d)(2) of the
13 Bipartisan Patient Protection Act of 2001 (re-
14 lating to medically reviewable decisions).

15 “(C) LIMITATION ON PUNITIVE DAM-
16 AGES.—

17 “(i) IN GENERAL.—Except as pro-
18 vided in clauses (ii) and (iii), with respect
19 to a cause of action described in subpara-
20 graph (A) brought with respect to a partic-
21 ipant or beneficiary, State law is super-
22 seded insofar as it provides any punitive,
23 exemplary, or similar damages if, as of the
24 time of the personal injury or death, all
25 the requirements of the following sections

1 of the Bipartisan Patient Protection Act of
2 2001 were satisfied with respect to the
3 participant or beneficiary:

4 “(I) Section 102 (relating to pro-
5 cedures for initial claims for benefits
6 and prior authorization determina-
7 tions).

8 “(II) Section 103 of such Act
9 (relating to internal appeals of claims
10 denials).

11 “(III) Section 104 of such Act
12 (relating to independent external ap-
13 peals procedures).

14 “(ii) EXCEPTION FOR CERTAIN AC-
15 TIONS FOR WRONGFUL DEATH.—Clause (i)
16 shall not apply with respect to an action
17 for wrongful death if the applicable State
18 law provides (or has been construed to pro-
19 vide) for damages in such an action which
20 are only punitive or exemplary in nature.

21 “(iii) EXCEPTION FOR WILLFUL OR
22 WANTON DISREGARD FOR THE RIGHTS OR
23 SAFETY OF OTHERS.—Clause (i) shall not
24 apply with respect to any cause of action
25 described in subparagraph (A) if, in such

1 action, the plaintiff establishes by clear
2 and convincing evidence that conduct car-
3 ried out by the defendant with willful or
4 wanton disregard for the rights or safety
5 of others was a proximate cause of the per-
6 sonal injury or wrongful death that is the
7 subject of the action.

8 “(2) DEFINITIONS.—For purposes of this sub-
9 section and subsection (e)—

10 “(A) GROUP HEALTH PLAN AND OTHER
11 RELATED TERMS.—The provisions of sections
12 732(d) and 733 apply for purposes of this sub-
13 section in the same manner as they apply for
14 purposes of part 7, except that the term ‘group
15 health plan’ includes a group health plan (as
16 defined in section 607(1)).

17 “(B) PERSONAL INJURY.—The term ‘per-
18 sonal injury’ means a physical injury and in-
19 cludes an injury arising out of the treatment
20 (or failure to treat) a mental illness or disease.

21 “(C) CLAIM FOR BENEFIT; DENIAL.—The
22 terms ‘claim for benefits’ and ‘denial of a claim
23 for benefits’ shall have the meaning provided
24 such terms under section 102(e) of the Bipar-
25 tisan Patient Protection Act of 2001.

1 “(3) EXCLUSION OF EMPLOYERS AND OTHER
2 PLAN SPONSORS.—

3 “(A) CAUSES OF ACTION AGAINST EM-
4 PLOYERS AND PLAN SPONSORS PRECLUDED.—
5 Subject to subparagraph (B), paragraph (1)
6 does not apply with respect to—

7 “(i) any cause of action against an
8 employer or other plan sponsor maintain-
9 ing the plan (or against an employee of
10 such an employer or sponsor acting within
11 the scope of employment), or

12 “(ii) a right of recovery, indemnity, or
13 contribution by a person against an em-
14 ployer or other plan sponsor (or such an
15 employee) for damages assessed against
16 the person pursuant to a cause of action to
17 which paragraph (1) applies.

18 “(B) CERTAIN CAUSES OF ACTION PER-
19 MITTED.—Notwithstanding subparagraph (A),
20 paragraph (1) applies with respect to any cause
21 of action described in paragraph (1) maintained
22 by a participant or beneficiary against an em-
23 ployer or other plan sponsor (or against an em-
24 ployee of such an employer or sponsor acting
25 within the scope of employment)—

1 “(i) in the case of any cause of action
2 based on a decision of the plan under sec-
3 tion 102 of the Bipartisan Patient Protec-
4 tion Act of 2001 upon consideration of a
5 claim for benefits or under section 103 of
6 such Act upon review of a denial of a claim
7 for benefits, to the extent there was direct
8 participation by the employer or other plan
9 sponsor (or employee) in the decision, or

10 “(ii) in the case of any cause of action
11 based on a failure to otherwise perform a
12 duty under the terms and conditions of the
13 plan with respect to a claim for benefits of
14 a participant or beneficiary, to the extent
15 there was direct participation by the em-
16 ployer or other plan sponsor (or employee)
17 in the failure.

18 “(C) DIRECT PARTICIPATION.—

19 “(i) DIRECT PARTICIPATION IN DECI-
20 SIONS.—For purposes of subparagraph
21 (B), the term ‘direct participation’ means,
22 in connection with a decision described in
23 subparagraph (B)(i) or a failure described
24 in subparagraph (B)(ii), the actual making
25 of such decision or the actual exercise of

1 control in making such decision or in the
2 conduct constituting the failure.

3 “(ii) RULES OF CONSTRUCTION.—For
4 purposes of clause (i), the employer or plan
5 sponsor (or employee) shall not be con-
6 strued to be engaged in direct participation
7 because of any form of decisionmaking or
8 other conduct that is merely collateral or
9 precedent to the decision described in sub-
10 paragraph (B)(i) on a particular claim for
11 benefits of a particular participant or bene-
12 ficiary or that is merely collateral or prece-
13 dent to the conduct constituting a failure
14 described in subparagraph (B)(ii) with re-
15 spect to a particular participant or bene-
16 ficiary, including (but not limited to)—

17 “(I) any participation by the em-
18 ployer or other plan sponsor (or em-
19 ployee) in the selection of the group
20 health plan or health insurance cov-
21 erage involved or the third party ad-
22 ministrator or other agent;

23 “(II) any engagement by the em-
24 ployer or other plan sponsor (or em-
25 ployee) in any cost-benefit analysis

1 undertaken in connection with the se-
2 lection of, or continued maintenance
3 of, the plan or coverage involved;

4 “(III) any participation by the
5 employer or other plan sponsor (or
6 employee) in the process of creating,
7 continuing, modifying, or terminating
8 the plan or any benefit under the
9 plan, if such process was not substan-
10 tially focused solely on the particular
11 situation of the participant or bene-
12 ficiary referred to in paragraph
13 (1)(A); and

14 “(IV) any participation by the
15 employer or other plan sponsor (or
16 employee) in the design of any benefit
17 under the plan, including the amount
18 of copayment and limits connected
19 with such benefit.

20 “(iv) IRRELEVANCE OF CERTAIN COL-
21 LATERAL EFFORTS MADE BY EMPLOYER
22 OR PLAN SPONSOR.—For purposes of this
23 subparagraph, an employer or plan sponsor
24 shall not be treated as engaged in direct
25 participation in a decision with respect to

1 any claim for benefits or denial thereof in
2 the case of any particular participant or
3 beneficiary solely by reason of—

4 “(I) any efforts that may have
5 been made by the employer or plan
6 sponsor to advocate for authorization
7 of coverage for that or any other par-
8 ticipant or beneficiary (or any group
9 of participants or beneficiaries), or

10 “(II) any provision that may
11 have been made by the employer or
12 plan sponsor for benefits which are
13 not covered under the terms and con-
14 ditions of the plan for that or any
15 other participant or beneficiary (or
16 any group of participants or bene-
17 ficiaries).

18 “(4) REQUIREMENT OF EXHAUSTION.—

19 “(A) IN GENERAL.—Except as provided in
20 this paragraph, paragraph (1) shall not apply
21 with respect to a cause of action described in
22 such paragraph in connection with any denial of
23 a claim for benefits of any individual until all
24 administrative processes under sections 102,
25 103, and 104 of the Bipartisan Patient Protec-

tion Act of 2001 (if applicable) have been exhausted.

“(B) LATE MANIFESTATION OF INJURY.—

The requirements under subparagraph (A) for a cause of action in connection with any denial of a claim for benefits shall be deemed satisfied, notwithstanding any failure to timely commence review under section 103 or 104 with respect to the denial, if the personal injury is first known (or first should have been known) to the individual (or the death occurs) after the latest date by which the applicable requirements of subparagraph (A) can be met in connection with such denial.

“(C) OCCURRENCE OF IMMEDIATE AN IRREPARABLE HARM OR DEATH PRIOR TO COMPLETION OF PROCESS.—

“(i) IN GENERAL.—The requirements of subparagraph (A) shall not apply if the action involves an allegation that immediate and irreparable harm or death was, or would be, caused by the denial of a claim for benefits prior to the completion of the administrative processes referred to

1 in subparagraph (A) with respect to such
2 denial.

3 “(ii) CONSTRUCTION.—Nothing in
4 clause (i) shall be construed to preclude—

5 “(I) continuation of such proc-
6 esses to their conclusion if so moved
7 by any party, and

8 “(II) consideration in such action
9 of the final decisions issued in such
10 processes.

11 “(iii) DEFINITION.—In clause (i), the
12 term ‘irreparable harm’, with respect to an
13 individual, means an injury or condition
14 that, regardless of whether the individual
15 receives the treatment that is the subject
16 of the denial, cannot be repaired in a man-
17 ner that would restore the individual to the
18 individual’s pre-injured condition.

19 “(D) RECEIPT OF BENEFITS DURING AP-
20 PEALS PROCESS.—Receipt by the participant or
21 beneficiary of the benefits involved in the claim
22 for benefits during the pendency of any admin-
23 istrative processes referred to in subparagraph
24 (A) or of any action commenced under this
25 subsection—

1 “(i) shall not preclude continuation of
2 all such administrative processes to their
3 conclusion if so moved by any party, and

4 “(ii) shall not preclude any liability
5 under subsection (a)(1)(C) and this sub-
6 section in connection with such claim.

7 “(5) TOLLING PROVISION.—The statute of limi-
8 tations for any cause of action arising under section
9 502(n) relating to a denial of a claim for benefits
10 that is the subject of an action brought in State
11 court shall be tolled until such time as the State
12 court makes a final disposition, including all ap-
13 peals, of whether such claim should properly be
14 within the jurisdiction of the State court. The tolling
15 period shall be determined by the applicable Federal
16 or State law, whichever period is greater.

17 “(6) EXCLUSION OF DIRECTED RECORD-
18 KEEPERS.—

19 “(A) IN GENERAL.—Subject to subpara-
20 graph (C), paragraph (1) shall not apply with
21 respect to a directed recordkeeper in connection
22 with a group health plan.

23 “(B) DIRECTED RECORDKEEPER.—For
24 purposes of this paragraph, the term ‘directed
25 recordkeeper’ means, in connection with a

1 group health plan, a person engaged in directed
2 recordkeeping activities pursuant to the specific
3 instructions of the plan or the employer or
4 other plan sponsor, including the distribution of
5 enrollment information and distribution of dis-
6 closure materials under this Act or title I of the
7 Bipartisan Patient Protection Act of 2001 and
8 whose duties do not include making decisions
9 on claims for benefits.

10 “(C) LIMITATION.—Subparagraph (A)
11 does not apply in connection with any directed
12 recordkeeper to the extent that the directed rec-
13 ordkeeper fails to follow the specific instruction
14 of the plan or the employer or other plan spon-
15 sor.

16 “(7) CONSTRUCTION.—Nothing in this sub-
17 section shall be construed as—

18 “(A) saving from preemption a cause of
19 action under State law for the failure to provide
20 a benefit for an item or service which is specifi-
21 cally excluded under the group health plan in-
22 volved, except to the extent that—

23 “(i) the application or interpretation
24 of the exclusion involves a determination
25 described in section 104(d)(2) of the Bi-

1 partisan Patient Protection Act of 2001,
2 or

3 “(ii) the provision of the benefit for
4 the item or service is required under Fed-
5 eral law or under applicable State law con-
6 sistent with subsection (b)(2)(B);

7 “(B) preempting a State law which re-
8 quires an affidavit or certificate of merit in a
9 civil action;

10 “(C) affecting a cause of action or remedy
11 under State law in connection with the provi-
12 sion or arrangement of excepted benefits (as de-
13 fined in section 733(c)), other than those de-
14 scribed in section 733(c)(2)(A); or

15 “(D) affecting a cause of action under
16 State law other than a cause of action described
17 in paragraph (1)(A).

18 “(8) PURCHASE OF INSURANCE TO COVER LI-
19 ABILITY.—Nothing in section 410 shall be construed
20 to preclude the purchase by a group health plan of
21 insurance to cover any liability or losses arising
22 under a cause of action described in paragraph
23 (1)(A).

1 “(e) RULES OF CONSTRUCTION RELATING TO
2 HEALTH CARE.—Nothing in this title shall be construed
3 as—

4 “(1) affecting any State law relating to the
5 practice of medicine or the provision of medical care,
6 or affecting any action based upon such a State law,

7 “(2) superseding any State law permitted under
8 section 152(b)(1)(A) of the Bipartisan Patient Pro-
9 tection Act of 2001, or

10 “(3) affecting any applicable State law with re-
11 spect to limitations on monetary damages.”.

12 (c) EFFECTIVE DATE.—The amendments made by
13 this section shall apply to acts and omissions (from which
14 a cause of action arises) occurring on or after the date
15 of the enactment of this Act.

16 **SEC. 303. LIMITATIONS ON ACTIONS.**

17 Section 502 of the Employee Retirement Income Se-
18 curity Act of 1974 (29 U.S.C. 1132) (as amended by sec-
19 tion 302(a)) is amended further by adding at the end the
20 following new subsection:

21 “(o) LIMITATIONS ON ACTIONS RELATING TO GROUP
22 HEALTH PLANS.—

23 “(1) IN GENERAL.—Except as provided in para-
24 graph (2), no action may be brought under sub-
25 section (a)(1)(B), (a)(2), or (a)(3) by a participant

1 or beneficiary seeking relief based on the application
2 of any provision in section 101, subtitle B, or sub-
3 title D of title I of the Bipartisan Patient Protection
4 Act of 2001 (as incorporated under section 714).

5 “(2) CERTAIN ACTIONS ALLOWABLE.—An ac-
6 tion may be brought under subsection (a)(1)(B),
7 (a)(2), or (a)(3) by a participant or beneficiary seek-
8 ing relief based on the application of section 101,
9 113, 114, 115, 116, 117, 118(a)(3), 119, or 120 of
10 the Bipartisan Patient Protection Act of 2001 (as
11 incorporated under section 714) to the individual
12 circumstances of that participant or beneficiary, ex-
13 cept that—

14 “(A) such an action may not be brought or
15 maintained as a class action; and

16 “(B) in such an action, relief may only
17 provide for the provision of (or payment of)
18 benefits, items, or services denied to the indi-
19 vidual participant or beneficiary involved (and
20 for attorney’s fees and the costs of the action,
21 at the discretion of the court) and shall not pro-
22 vide for any other relief to the participant or
23 beneficiary or for any relief to any other person.

1 “(3) OTHER PROVISIONS UNAFFECTED.—Noth-
 2 ing in this subsection shall be construed as affecting
 3 subsections (a)(1)(C) and (n) or section 514(d).

4 “(4) ENFORCEMENT BY SECRETARY UNAF-
 5 FECTED.—Nothing in this subsection shall be con-
 6 strued as affecting any action brought by the Sec-
 7 retary.”.

8 **TITLE IV—AMENDMENTS TO THE**
 9 **INTERNAL REVENUE CODE**
 10 **OF 1986**

11 **Subtitle A—Application of Patient**
 12 **Protection Provisions**

13 **SEC. 401. APPLICATION TO GROUP HEALTH PLANS UNDER**
 14 **THE INTERNAL REVENUE CODE OF 1986.**

15 Subchapter B of chapter 100 of the Internal Revenue
 16 Code of 1986 is amended—

17 (1) in the table of sections, by inserting after
 18 the item relating to section 9812 the following new
 19 item:

 “Sec. 9813. Standard relating to patients’ bill of rights.”;

20 and

21 (2) by inserting after section 9812 the fol-
 22 lowing:

1 **“SEC. 9813. STANDARD RELATING TO PATIENTS’ BILL OF**
 2 **RIGHTS.**

3 “A group health plan shall comply with the require-
 4 ments of title I of the Bipartisan Patient Protection Act
 5 of 2001 (as in effect as of the date of the enactment of
 6 such Act), and such requirements shall be deemed to be
 7 incorporated into this section.”.

8 **SEC. 402. CONFORMING ENFORCEMENT FOR WOMEN’S**
 9 **HEALTH AND CANCER RIGHTS.**

10 Subchapter B of chapter 100 of the Internal Revenue
 11 Code of 1986, as amended by section 401, is further
 12 amended—

13 (1) in the table of sections, by inserting after
 14 the item relating to section 9813 the following new
 15 item:

“Sec. 9814. Standard relating to women’s health and cancer
 rights.”;

16 and

17 (2) by inserting after section 9813 the fol-
 18 lowing:

19 **“SEC. 9814. STANDARD RELATING TO WOMEN’S HEALTH**
 20 **AND CANCER RIGHTS.**

21 “The provisions of section 713 of the Employee Re-
 22 tirement Income Security Act of 1974 (as in effect as of
 23 the date of the enactment of this section) shall apply to
 24 group health plans as if included in this subchapter.”.

1 **Subtitle B—Health Care Coverage**
 2 **Access Tax Incentives**

3 **SEC. 411. EXPANDED AVAILABILITY OF ARCHER MSAS.**

4 (a) EXTENSION OF PROGRAM.—Paragraphs (2) and
 5 (3)(B) of section 220(i) of the Internal Revenue Code of
 6 1986 (defining cut-off year) are each amended by striking
 7 “2002” each place it appears and inserting “2004”.

8 (b) INCREASE IN NUMBER OF PERMITTED ACCOUNT
 9 PARTICIPANTS.—

10 (1) IN GENERAL.—Subsection (j) of section 220
 11 of such Code is amended by redesignating para-
 12 graphs (3), (4), and (5) as paragraphs (4), (5), and
 13 (6) and by inserting after paragraph (2) the fol-
 14 lowing new paragraph:

15 “(3) DETERMINATION OF WHETHER LIMIT EX-
 16 CEEDED FOR YEARS AFTER 2001.—

17 “(A) IN GENERAL.—The numerical limita-
 18 tion for any year after 2001 is exceeded if the
 19 sum of—

20 “(i) the number of Archer MSA re-
 21 turns filed on or before April 15 of such
 22 calendar year for taxable years ending with
 23 or within the preceding calendar year, plus

24 “(ii) the Secretary’s estimate (deter-
 25 mined on the basis of the returns described

in clause (i)) of the number of Archer MSA returns for such taxable years which will be filed after such date, exceeds 1,000,000. For purposes of the preceding sentence, the term ‘Archer MSA return’ means any return on which any exclusion is claimed under section 106(b) or any deduction is claimed under this section.

“(B) ALTERNATIVE COMPUTATION OF LIMITATION.—The numerical limitation for any year after 2001 is also exceeded if the sum of—

“(i) 90 percent of the sum determined under subparagraph (A) for such calendar year, plus

“(ii) the product of 2.5 and the number of medical savings accounts established during the portion of such year preceding July 1 (based on the reports required under paragraph (5)) for taxable years beginning in such year,

exceeds 1,000,000”.

(2) CONFORMING AMENDMENTS.—

(A) Clause (ii) of section 220(j)(2)(B) of such Code is amended by striking “paragraph (4)” and inserting “paragraph (5)”.

1 (B) Subparagraph (A) of section 220(j)(4)
2 of such Code is amended by striking “and
3 2001” and inserting “2001, 2002, and 2003”.

4 (c) INCREASE IN SIZE OF ELIGIBLE EMPLOYERS.—
5 Subparagraph (A) of section 220(c)(4) of such Code is
6 amended by striking “50 or fewer employees” and insert-
7 ing “100 or fewer employees”.

8 (d) EFFECTIVE DATE.—The amendments made by
9 this section shall take effect on the date of the enactment
10 of this Act.

11 (e) GAO STUDY.—Not later than 1 year after the
12 date of the enactment of this Act, the Comptroller General
13 of the United States shall prepare and submit a report
14 to the Committee on Ways and Means of the House of
15 Representatives and the Committee on Finance of the
16 Senate on the impact of Archer MSAs on the cost of con-
17 ventional insurance (especially in those areas where there
18 are higher numbers of such accounts) and on adverse se-
19 lection and health care costs.

20 **SEC. 412. DEDUCTION FOR 100 PERCENT OF HEALTH IN-**
21 **SURANCE COSTS OF SELF-EMPLOYED INDIV-**
22 **VIDUALS.**

23 (a) IN GENERAL.—Paragraph (1) of section 162(l)
24 of the Internal Revenue Code of 1986 is amended to read
25 as follows:

1 “(1) ALLOWANCE OF DEDUCTION.—In the case
2 of an individual who is an employee within the
3 meaning of section 401(c)(1), there shall be allowed
4 as a deduction under this section an amount equal
5 to 100 percent of the amount paid during the tax-
6 able year for insurance which constitutes medical
7 care for the taxpayer and the taxpayer’s spouse and
8 dependents.”.

9 (b) EFFECTIVE DATE.—The amendment made by
10 this section shall apply to taxable years beginning after
11 December 31, 2001.

12 **SEC. 413. CREDIT FOR HEALTH INSURANCE EXPENSES OF**
13 **SMALL BUSINESSES.**

14 (a) IN GENERAL.—Subpart D of part IV of sub-
15 chapter A of chapter 1 of the Internal Revenue Code of
16 1986 (relating to business-related credits) is amended by
17 adding at the end the following:

18 **“SEC. 45E. SMALL BUSINESS HEALTH INSURANCE EX-**
19 **PENSES.**

20 “(a) GENERAL RULE.—For purposes of section 38,
21 in the case of a small employer, the health insurance credit
22 determined under this section for the taxable year is an
23 amount equal to the applicable percentage of the expenses
24 paid by the taxpayer during the taxable year for health

1 insurance coverage for such year provided under a new
2 health plan for employees of such employer.

3 “(b) APPLICABLE PERCENTAGE.—For purposes of
4 subsection (a), the applicable percentage is—

5 “(1) in the case of insurance purchased as a
6 member of a qualified health benefit purchasing coa-
7 lition (as defined in section 9841), 30 percent, and

8 “(2) in the case of insurance not described in
9 paragraph (1), 20 percent.

10 “(c) LIMITATIONS.—

11 “(1) PER EMPLOYEE DOLLAR LIMITATION.—

12 The amount of expenses taken into account under
13 subsection (a) with respect to any employee for any
14 taxable year shall not exceed—

15 “(A) \$2,000 in the case of self-only cov-
16 erage, and

17 “(B) \$5,000 in the case of family coverage.

18 In the case of an employee who is covered by a new
19 health plan of the employer for only a portion of
20 such taxable year, the limitation under the preceding
21 sentence shall be an amount which bears the same
22 ratio to such limitation (determined without regard
23 to this sentence) as such portion bears to the entire
24 taxable year.

1 “(2) PERIOD OF COVERAGE.—Expenses may be
2 taken into account under subsection (a) only with
3 respect to coverage for the 4-year period beginning
4 on the date the employer establishes a new health
5 plan.

6 “(d) DEFINITIONS.—For purposes of this section—

7 “(1) HEALTH INSURANCE COVERAGE.—The
8 term ‘health insurance coverage’ has the meaning
9 given such term by section 9832(b)(1).

10 “(2) NEW HEALTH PLAN.—

11 “(A) IN GENERAL.—The term ‘new health
12 plan’ means any arrangement of the employer
13 which provides health insurance coverage to em-
14 ployees if—

15 “(i) such employer (and any prede-
16 cessor employer) did not establish or main-
17 tain such arrangement (or any similar ar-
18 rangement) at any time during the 2 tax-
19 able years ending prior to the taxable year
20 in which the credit under this section is
21 first allowed, and

22 “(ii) such arrangement provides
23 health insurance coverage to at least 70
24 percent of the qualified employees of such
25 employer.

1 “(B) QUALIFIED EMPLOYEE.—

2 “(i) IN GENERAL.—The term ‘quali-
3 fied employee’ means any employee of an
4 employer if the annual rate of such em-
5 ployee’s compensation (as defined in sec-
6 tion 414(s)) exceeds \$10,000.

7 “(ii) TREATMENT OF CERTAIN EM-
8 PLOYEES.—The term ‘employee’ shall in-
9 clude a leased employee within the mean-
10 ing of section 414(n).

11 “(3) SMALL EMPLOYER.—The term ‘small em-
12 ployer’ has the meaning given to such term by sec-
13 tion 4980D(d)(2); except that only qualified employ-
14 ees shall be taken into account.

15 “(e) SPECIAL RULES.—

16 “(1) CERTAIN RULES MADE APPLICABLE.—For
17 purposes of this section, rules similar to the rules of
18 section 52 shall apply.

19 “(2) AMOUNTS PAID UNDER SALARY REDUC-
20 TION ARRANGEMENTS.—No amount paid or incurred
21 pursuant to a salary reduction arrangement shall be
22 taken into account under subsection (a).

23 “(f) TERMINATION.—This section shall not apply to
24 expenses paid or incurred by an employer with respect to

1 any arrangement established on or after January 1,
2 2010.”.

3 (b) CREDIT TO BE PART OF GENERAL BUSINESS
4 CREDIT.—Section 38(b) of such Code (relating to current
5 year business credit) is amended by striking “plus” at the
6 end of paragraph (12), by striking the period at the end
7 of paragraph (13) and inserting “, plus”, and by adding
8 at the end the following:

9 “(14) in the case of a small employer (as de-
10 fined in section 45E(d)(3)), the health insurance
11 credit determined under section 45E(a).”.

12 (c) NO CARRYBACKS.—Subsection (d) of section 39
13 of such Code (relating to carryback and carryforward of
14 unused credits) is amended by adding at the end the fol-
15 lowing:

16 “(10) NO CARRYBACK OF SECTION 45E CREDIT
17 BEFORE EFFECTIVE DATE.—No portion of the un-
18 used business credit for any taxable year which is
19 attributable to the employee health insurance ex-
20 penses credit determined under section 45E may be
21 carried back to a taxable year ending before the date
22 of the enactment of section 45E.”.

23 (d) DENIAL OF DOUBLE BENEFIT.—Section 280C of
24 such Code is amended by adding at the end the following
25 new subsection:

1 “(d) CREDIT FOR SMALL BUSINESS HEALTH INSUR-
2 ANCE EXPENSES.—

3 “(1) IN GENERAL.—No deduction shall be al-
4 lowed for that portion of the expenses (otherwise al-
5 lowable as a deduction) taken into account in deter-
6 mining the credit under section 45E for the taxable
7 year which is equal to the amount of the credit de-
8 termined for such taxable year under section
9 45E(a).

10 “(2) CONTROLLED GROUPS.—Persons treated
11 as a single employer under subsection (a) or (b) of
12 section 52 shall be treated as 1 person for purposes
13 of this section.”.

14 (e) CLERICAL AMENDMENT.—The table of sections
15 for subpart D of part IV of subchapter A of chapter 1
16 of such Code is amended by adding at the end the fol-
17 lowing:

 “Sec. 45E. Small business health insurance expenses.”.

18 (f) EFFECTIVE DATE.—The amendments made by
19 this section shall apply to amounts paid or incurred in tax-
20 able years beginning after December 31, 2001, for ar-
21 rangements established after the date of the enactment
22 of this Act.

1 **SEC. 414. CERTAIN GRANTS BY PRIVATE FOUNDATIONS TO**
2 **QUALIFIED HEALTH BENEFIT PURCHASING**
3 **COALITIONS.**

4 (a) IN GENERAL.—Section 4942 of the Internal Rev-
5 enue Code of 1986 (relating to taxes on failure to dis-
6 tribute income) is amended by adding at the end the fol-
7 lowing:

8 “(k) CERTAIN QUALIFIED HEALTH BENEFIT PUR-
9 CHASING COALITION DISTRIBUTIONS.—

10 “(1) IN GENERAL.—For purposes of subsection
11 (g), sections 170, 501, 507, 509, and 2522, and this
12 chapter, a qualified health benefit purchasing coali-
13 tion distribution by a private foundation shall be
14 considered to be a distribution for a charitable pur-
15 pose.

16 “(2) QUALIFIED HEALTH BENEFIT PUR-
17 CHASING COALITION DISTRIBUTION.—For purposes
18 of paragraph (1)—

19 “(A) IN GENERAL.—The term ‘qualified
20 health benefit purchasing coalition distribution’
21 means any amount paid or incurred by a pri-
22 vate foundation to or on behalf of a qualified
23 health benefit purchasing coalition (as defined
24 in section 9841) for purposes of payment or re-
25 imbursement of amounts paid or incurred in

1 connection with the establishment and mainte-
 2 nance of such coalition.

3 “(B) EXCLUSIONS.—Such term shall not
 4 include any amount used by a qualified health
 5 benefit purchasing coalition (as so defined)—

6 “(i) for the purchase of real property,

7 “(ii) as payment to, or for the benefit
 8 of, members (or employees or affiliates of
 9 such members) of such coalition, or

10 “(iii) for any expense paid or incurred
 11 more than 48 months after the date of es-
 12 tablishment of such coalition.

13 “(3) TERMINATION.—This subsection shall not
 14 apply—

15 “(A) to qualified health benefit purchasing
 16 coalition distributions paid or incurred after
 17 December 31, 2009, and

18 “(B) with respect to start-up costs of a co-
 19 alition which are paid or incurred after Decem-
 20 ber 31, 2010.”.

21 (b) QUALIFIED HEALTH BENEFIT PURCHASING CO-
 22 ALITION.—

23 (1) IN GENERAL.—Chapter 100 of such Code
 24 (relating to group health plan requirements) is

1 amended by adding at the end the following new
 2 subchapter:

3 **“Subchapter D—Qualified Health Benefit**
 4 **Purchasing Coalition**

“Sec. 9841. Qualified health benefit purchasing coalition.

5 **“SEC. 9841. QUALIFIED HEALTH BENEFIT PURCHASING CO-**
 6 **ALITION.**

7 “(a) IN GENERAL.—A qualified health benefit pur-
 8 chasing coalition is a private not-for-profit corporation
 9 which—

10 “(1) sells health insurance through State li-
 11 censed health insurance issuers in the State in which
 12 the employers to which such coalition is providing
 13 insurance are located, and

14 “(2) establishes to the Secretary, under State
 15 certification procedures or other procedures as the
 16 Secretary may provide by regulation, that such coali-
 17 tion meets the requirements of this section.

18 “(b) BOARD OF DIRECTORS.—

19 “(1) IN GENERAL.—Each purchasing coalition
 20 under this section shall be governed by a Board of
 21 Directors.

22 “(2) ELECTION.—The Secretary shall establish
 23 procedures governing election of such Board.

1 “(3) MEMBERSHIP.—The Board of Directors
2 shall—

3 “(A) be composed of representatives of the
4 members of the coalition, in equal number, in-
5 cluding small employers and employee rep-
6 resentatives of such employers, but

7 “(B) not include other interested parties,
8 such as service providers, health insurers, or in-
9 surance agents or brokers which may have a
10 conflict of interest with the purposes of the coa-
11 lition.

12 “(c) MEMBERSHIP OF COALITION.—

13 “(1) IN GENERAL.—A purchasing coalition
14 shall accept all small employers residing within the
15 area served by the coalition as members if such em-
16 ployers request such membership.

17 “(2) OTHER MEMBERS.—The coalition, at the
18 discretion of its Board of Directors, may be open to
19 individuals and large employers.

20 “(3) VOTING.—Members of a purchasing coali-
21 tion shall have voting rights consistent with the rules
22 established by the State.

23 “(d) DUTIES OF PURCHASING COALITIONS.—Each
24 purchasing coalition shall—

1 “(1) enter into agreements with small employ-
2 ers (and, at the discretion of its Board, with individ-
3 uals and other employers) to provide health insur-
4 ance benefits to employees and retirees of such em-
5 ployers,

6 “(2) where feasible, enter into agreements with
7 3 or more unaffiliated, qualified licensed health
8 plans, to offer benefits to members,

9 “(3) offer to members at least 1 open enroll-
10 ment period of at least 30 days per calendar year,

11 “(4) serve a significant geographical area and
12 market to all eligible members in that area, and

13 “(5) carry out other functions provided for
14 under this section.

15 “(e) LIMITATION ON ACTIVITIES.—A purchasing coa-
16 lition shall not—

17 “(1) perform any activity (including certifi-
18 cation or enforcement) relating to compliance or li-
19 censing of health plans,

20 “(2) assume insurance or financial risk in rela-
21 tion to any health plan, or

22 “(3) perform other activities identified by the
23 State as being inconsistent with the performance of
24 its duties under this section.

1 “(f) ADDITIONAL REQUIREMENTS FOR PURCHASING
2 COALITIONS.—As provided by the Secretary in regula-
3 tions, a purchasing coalition shall be subject to require-
4 ments similar to the requirements of a group health plan
5 under this chapter.

6 “(g) RELATION TO OTHER LAWS.—

7 “(1) PREEMPTION OF STATE FICTITIOUS
8 GROUP LAWS.—Requirements (commonly referred to
9 as fictitious group laws) relating to grouping and
10 similar requirements for health insurance coverage
11 are preempted to the extent such requirements im-
12 pede the establishment and operation of qualified
13 health benefit purchasing coalitions.

14 “(2) ALLOWING SAVINGS TO BE PASSED
15 THROUGH.—Any State law that prohibits health in-
16 surance issuers from reducing premiums on health
17 insurance coverage sold through a qualified health
18 benefit purchasing coalition to reflect administrative
19 savings is preempted. This paragraph shall not be
20 construed to preempt State laws that impose restric-
21 tions on premiums based on health status, claims
22 history, industry, age, gender, or other underwriting
23 factors.

24 “(3) NO WAIVER OF HIPAA REQUIREMENTS.—
25 Nothing in this section shall be construed to change

1 the obligation of health insurance issuers to comply
2 with the requirements of title XXVII of the Public
3 Health Service Act with respect to health insurance
4 coverage offered to small employers in the small
5 group market through a qualified health benefit pur-
6 chasing coalition.

7 “(h) DEFINITION OF SMALL EMPLOYER.—For pur-
8 poses of this section—

9 “(1) IN GENERAL.—The term ‘small employer’
10 means, with respect to any calendar year, any em-
11 ployer if such employer employed an average of at
12 least 2 and not more than 50 qualified employees on
13 business days during either of the 2 preceding cal-
14 endar years. For purposes of the preceding sentence,
15 a preceding calendar year may be taken into account
16 only if the employer was in existence throughout
17 such year.

18 “(2) EMPLOYERS NOT IN EXISTENCE IN PRE-
19 CEDING YEAR.—In the case of an employer which
20 was not in existence throughout the 1st preceding
21 calendar year, the determination under paragraph
22 (1) shall be based on the average number of quali-
23 fied employees that it is reasonably expected such
24 employer will employ on business days in the current
25 calendar year.”.

1 (2) CONFORMING AMENDMENT.—The table of
 2 subchapters for chapter 100 of such Code is amend-
 3 ed by adding at the end the following item:

 “Subchapter D. Qualified health benefit purchasing coalition.”.

4 (c) EFFECTIVE DATE.—The amendment made by
 5 subsection (a) shall apply to taxable years beginning after
 6 December 31, 2001.

7 **SEC. 415. STATE GRANT PROGRAM FOR MARKET INNOVA-**
 8 **TION.**

9 (a) IN GENERAL.—The Secretary of Health and
 10 Human Services (in this section referred to as the “Sec-
 11 retary”) shall establish a program (in this section referred
 12 to as the “program”) to award demonstration grants
 13 under this section to States to allow States to demonstrate
 14 the effectiveness of innovative ways to increase access to
 15 health insurance through market reforms and other inno-
 16 vative means. Such innovative means may include (and are
 17 not limited to) any of the following:

18 (1) Alternative group purchasing or pooling ar-
 19 rangements, such as a purchasing cooperatives for
 20 small businesses, reinsurance pools, or high risk
 21 pools.

22 (2) Individual or small group market reforms.

23 (3) Consumer education and outreach.

24 (4) Subsidies to individuals, employers, or both,
 25 in obtaining health insurance.

1 (b) SCOPE; DURATION.—The program shall be lim-
2 ited to not more than 10 States and to a total period of
3 5 years, beginning on the date the first demonstration
4 grant is made.

5 (c) CONDITIONS FOR DEMONSTRATION GRANTS.—

6 (1) IN GENERAL.—The Secretary may not pro-
7 vide for a demonstration grant to a State under the
8 program unless the Secretary finds that under the
9 proposed demonstration grant—

10 (A) the State will provide for demonstrated
11 increase of access for some portion of the exist-
12 ing uninsured population through a market in-
13 novation (other than merely through a financial
14 expansion of a program initiated before the
15 date of the enactment of this Act);

16 (B) the State will comply with applicable
17 Federal laws;

18 (C) the State will not discriminate among
19 participants on the basis of any health status-
20 related factor (as defined in section 2791(d)(9)
21 of the Public Health Service Act), except to the
22 extent a State wishes to focus on populations
23 that otherwise would not obtain health insur-
24 ance because of such factors; and

1 (D) the State will provide for such evalua-
2 tion, in coordination with the evaluation re-
3 quired under subsection (d), as the Secretary
4 may specify.

5 (2) APPLICATION.—The Secretary shall not
6 provide a demonstration grant under the program to
7 a State unless—

8 (A) the State submits to the Secretary
9 such an application, in such a form and man-
10 ner, as the Secretary specifies;

11 (B) the application includes information
12 regarding how the demonstration grant will ad-
13 dress issues such as governance, targeted popu-
14 lation, expected cost, and the continuation after
15 the completion of the demonstration grant pe-
16 riod; and

17 (C) the Secretary determines that the dem-
18 onstration grant will be used consistent with
19 this section.

20 (3) FOCUS.—A demonstration grant proposal
21 under section need not cover all uninsured individ-
22 uals in a State or all health care benefits with re-
23 spect to such individuals.

24 (d) EVALUATION.—The Secretary shall enter into a
25 contract with an appropriate entity outside the Depart-

1 ment of Health and Human Services to conduct an overall
2 evaluation of the program at the end of the program pe-
3 riod. Such evaluation shall include an analysis of improve-
4 ments in access, costs, quality of care, or choice of cov-
5 erage, under different demonstration grants.

6 (e) OPTION TO PROVIDE FOR INITIAL PLANNING
7 GRANTS.—Notwithstanding the previous provisions of this
8 section, under the program the Secretary may provide for
9 a portion of the amounts appropriated under subsection
10 (f) (not to exceed \$5,000,000) to be made available to any
11 State for initial planning grants to permit States to de-
12 velop demonstration grant proposals under the previous
13 provisions of this section.

14 (f) AUTHORIZATION OF APPROPRIATIONS.—There
15 are authorized to be appropriated \$100,000,000 for each
16 fiscal year to carry out this section. Amounts appropriated
17 under this subsection shall remain available until ex-
18 pended.

19 (g) STATE DEFINED.—For purposes of this section,
20 the term “State” has the meaning given such term for
21 purposes of title XIX of the Social Security Act.

1 **TITLE V—EFFECTIVE DATES; CO-**
2 **ORDINATION IN IMPLEMEN-**
3 **TATION**

4 **SEC. 501. EFFECTIVE DATES.**

5 (a) GROUP HEALTH COVERAGE.—

6 (1) IN GENERAL.—Subject to paragraph (2)
7 and subsection (d), the amendments made by sec-
8 tions 201(a), 301, 303, and 401 and 402 (and title
9 I insofar as it relates to such sections) shall apply
10 with respect to group health plans, and health insur-
11 ance coverage offered in connection with group
12 health plans, for plan years beginning on or after
13 January 1, 2002 (in this section referred to as the
14 “general effective date”).

15 (2) TREATMENT OF COLLECTIVE BARGAINING
16 AGREEMENTS.—In the case of a group health plan
17 maintained pursuant to one or more collective bar-
18 gaining agreements between employee representa-
19 tives and one or more employers ratified before the
20 date of the enactment of this Act, the amendments
21 made by sections 201(a), 301, 303, and 401 and
22 402 (and title I insofar as it relates to such sections)
23 shall not apply to plan years beginning before the
24 later of—

1 (A) the date on which the last collective
 2 bargaining agreements relating to the plan ter-
 3 minates (determined without regard to any ex-
 4 tension thereof agreed to after the date of the
 5 enactment of this Act); or

6 (B) the general effective date.

7 For purposes of subparagraph (A), any plan amend-
 8 ment made pursuant to a collective bargaining
 9 agreement relating to the plan which amends the
 10 plan solely to conform to any requirement added by
 11 this division shall not be treated as a termination of
 12 such collective bargaining agreement.

13 (b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—
 14 Subject to subsection (d), the amendments made by sec-
 15 tion 202 shall apply with respect to individual health in-
 16 surance coverage offered, sold, issued, renewed, in effect,
 17 or operated in the individual market on or after the gen-
 18 eral effective date.

19 (c) TREATMENT OF RELIGIOUS NONMEDICAL PRO-
 20 VIDERS.—

21 (1) IN GENERAL.—Nothing in this Act (or the
 22 amendments made thereby) shall be construed to—

23 (A) restrict or limit the right of group
 24 health plans, and of health insurance issuers of-

1 fering health insurance coverage, to include as
2 providers religious nonmedical providers;

3 (B) require such plans or issuers to—

4 (i) utilize medically based eligibility
5 standards or criteria in deciding provider
6 status of religious nonmedical providers;

7 (ii) use medical professionals or cri-
8 teria to decide patient access to religious
9 nonmedical providers;

10 (iii) utilize medical professionals or
11 criteria in making decisions in internal or
12 external appeals regarding coverage for
13 care by religious nonmedical providers; or

14 (iv) compel a participant or bene-
15 ficiary to undergo a medical examination
16 or test as a condition of receiving health
17 insurance coverage for treatment by a reli-
18 gious nonmedical provider; or

19 (C) require such plans or issuers to ex-
20 clude religious nonmedical providers because
21 they do not provide medical or other required
22 data, if such data is inconsistent with the reli-
23 gious nonmedical treatment or nursing care
24 provided by the provider.

1 (2) RELIGIOUS NONMEDICAL PROVIDER.—For
2 purposes of this subsection, the term “religious non-
3 medical provider” means a provider who provides no
4 medical care but who provides only religious non-
5 medical treatment or religious nonmedical nursing
6 care.

7 (d) TRANSITION FOR NOTICE REQUIREMENT.—The
8 disclosure of information required under section 121 of
9 this Act shall first be provided pursuant to—

10 (1) subsection (a) with respect to a group
11 health plan that is maintained as of the general ef-
12 fective date, not later than 30 days before the begin-
13 ning of the first plan year to which title I applies
14 in connection with the plan under such subsection;
15 or

16 (2) subsection (b) with respect to a individual
17 health insurance coverage that is in effect as of the
18 general effective date, not later than 30 days before
19 the first date as of which title I applies to the cov-
20 erage under such subsection.

21 **SEC. 502. COORDINATION IN IMPLEMENTATION.**

22 The Secretary of Labor, the Secretary of Health and
23 Human Services, and the Secretary of the Treasury shall
24 ensure, through the execution of an interagency memo-
25 randum of understanding among such Secretaries, that—

1 (1) regulations, rulings, and interpretations
2 issued by such Secretaries relating to the same mat-
3 ter over which such Secretaries have responsibility
4 under the provisions of this division (and the amend-
5 ments made thereby) are administered so as to have
6 the same effect at all times; and

7 (2) coordination of policies relating to enforcing
8 the same requirements through such Secretaries in
9 order to have a coordinated enforcement strategy
10 that avoids duplication of enforcement efforts and
11 assigns priorities in enforcement.

12 **SEC. 503. SEVERABILITY.**

13 If any provision of this Act, an amendment made by
14 this Act, or the application of such provision or amend-
15 ment to any person or circumstance is held to be unconsti-
16 tutional, the remainder of this Act, the amendments made
17 by this Act, and the application of the provisions of such
18 to any person or circumstance shall not be affected there-
19 by.

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